Proceedings of the Conference

Food Quality Protection Act

Organized by the Pesticides Section, Region I,
United States Environmental Protection Agency

Sponsored by:

EPA Region I
New England State Cooperative Extension Systems
New England State Pesticide Departments

At

Westford, Massachusetts

March 3rd, 1999

Introduction

The conference was initiated by Region I of the Environmental Protection Agency to get information to, and feedback from, New England stakeholders on implementation of the Food Quality Protection Act of 1996. The conference was preceded by an April, 1998 meeting on the Food Quality Protection Act between Dr. Lynn Goldman, EPA Assistant Administrator for Prevention, Pesticides, and Toxic Substances and a group of New England stakeholders. (See Appendix 6) The issues raised at that meeting made it evident that a conference on FQPA would be useful to a wider New England audience.

Eighty representatives from commodity groups, food producers, government agencies, academia, state agencies and public interest groups attended the conference which was held March 3, 1999 at the Westford Regency Hotel and Conference Center in Westford, MA.

Mindy Lubber, Deputy Regional Administrator, provided the keynote speech. Conference talks and panel discussions covered governmental efforts to both implement and spread the word on the Food Quality Protection Act: the current status of EPA's implementation of the Act, EPA's data needs and its risk assessment process, EPA headquarters and Regional activities in spreading the word on FQPA, FDA's program to monitor pesticide residues on food, and the impact of the Act on drinking water. Discussion sessions were held on EPA's outreach efforts, the "risk cup", endocrine disruptors, and data requirements.

Rob Koethe and Andy Triolo shared moderator duties during the morning session.

These proceedings include edited transcripts of the talks and panel member discussions. A summary of the break-out discussion on endocrine disruptors as well as on the outreach discussion are included. In appendices a summary of the discussion between Dr. Goldman and a group of 30 stakeholders is provided. Biographies of the speakers and panel members and a list of attendees is also included.

EPA Food Quality Protection Act Conference

Summaries of Talks

Introduction

Robert Koethe, Moderator

Hello. I'm Rob Koethe and I'm the EPA-New England pesticide expert. I want to welcome you to our conference. We at EPA-New England, together with our co-sponsors, the University of Massachusetts Extension System, Massachusetts Department of Food and Agriculture, as well as the pesticide regulatory agencies and extension services from all the other New England states, are holding this conference to improve your understanding of the new food safety law, the Food Quality Protection Act.

I would like to give special thanks to Natalia Clifton and the University of Massachusetts Pesticide Education program for handling the conference registrations.

While we've been planning this conference for a long time, it turns out that the conference is incredibly timely since articles and issues relating to pesticide residues in food have been in the news a lot over the last few weeks. The main objective of this conference is to inform you about pesticide and food issues within the framework of the Food Quality Protection Act. We will also provide you with an opportunity to speak with professionals in the EPA pesticide program who are responsible for implementing the changes required by the Act.

We have about 80 people here representing a wide range of perspectives, including pesticide regulatory agencies, university extension specialists, and other university staff; we also have Public Health Department people, environmental interest groups and members of the general public attending. I think the composition of our audience is unusual and I think we'll have some interesting questions and discussion during the session.

Turning to the agenda which is in your packet, we do have a last-minute change. One of our speakers, Dr. Chris DiFonzo of Michigan State University, had airline problems and won't be here; however, LeBelle Hicks of the Maine Board of Pesticide Control, has graciously volunteered to lead Chris' break-out session on endocrine disruptors.

Today's program is structured to go from the big picture to special topics. We'll start with two

speakers who have key responsibilities relative to the Food Quality Protection Act at EPA headquarters. Then we'll have a group of panelists who represent federal agencies, who will discuss their perspectives and responsibilities relative to the Act. In the afternoon we split up into concurrent sessions in which four topics will be covered. Three of them will be repeated twice; the endocrine disruptor session will only be run once. Later in the program just before lunch we'll announce the specific room assignments for the break out sessions.

Now I'd like to introduce Mindy Lubber, our keynote speaker. Mindy is the Deputy Regional Administrator for EPA-Region I, New England. Mindy is responsible for the administration and management of the 800-person, $450 million budget office as well as for overseeing the programmatic policy and legal work of the region. She personally directs the region's external affairs programs, which includes media relations and intergovernmental affairs. She's a member of the Region I senior management council. In the past she served as president of Green Century Capital Management, an investment firm dedicated to investing in environmentally responsible companies which donates all of its net revenues to supporting environmental advocacy. Mindy was a senior advisor to former Massachusetts Governor Michael Dukakis and was part of the team that ran his presidential campaign. She's held various positions with the Massachusetts Public Interest Research Group including Chairwoman of the Board of Directors and Legislative Directors. Mindy holds a bachelor's and master's in business administration and a law degree. She's a member of the Massachusetts Bar. Mindy, will you please come up and address us?

Keynote Address

Mindy Lubber, Deputy Regional Administrator

Good morning. Thanks for being here. I'm certainly glad to be here. It is a terrific topic to be talking about. My comments will be brief. I want to offer some introductory comments on the day, the Act, and how this ties in with the rest of the mission of the Environmental Protection Agency. But today's conference, and more importantly perhaps, the Food Quality Protection Act itself, is truly an exciting piece of business to be talking about, and an exciting place for us to be going with all of you in terms of how we implement it. And it could not be a more compelling subject.

There's often this issue, and we ran into it in spades during the Congressional attacks when our budgets were being reduced three or four years ago, people often said, I can't get my hands around what you do. How does it relate to my daily life? You talk about pollution prevention; I can't figure out what that means. Enforcement of certain polluters I understand but I don't necessarily see the connection.

I always use the Eleanor Lubber test, Eleanor being my mother; a middle-of-the-road, educated person. She certainly doesn't know all the intimate details of the Agency. If she gets it and thinks

it's important, it means we're communicating to the rest of the world; to the average citizens who very definitely care about the environment, who could not care more about their children's health and safety. When you talk about protecting the food their children are eating, it is the kind of subject matter that resonates, that will allow us to involve the public in an even greater way in the work that we do, and I believe that involvement always makes for richer, smarter and more compelling decisions.

So for any number of reasons, I am pleased that we are getting more and more and engaged in the Food Quality Protection Act through this conference and obviously in other ways as we implement it. It's also a very timely conference. I am a friend of newspapers and try to read two or three a day, as well as something in the office we call the Green Wire which gives us capsules of the highlighted news stories all across the country. It is clear to me that food safety-related issues have been in the news for the last month or two on an almost daily basis, in headlines from Los Angeles to Mississippi to Texas to Utah to Ohio to New York. We are seeing news stories, good and bad, about what's going on with food quality, with the pesticides on food and so on. It is on the public agenda and that is a good time to be tackling an issue, when it's on the public agenda.

Less than a month ago EPA released its right-to-know brochure on pesticides and food. Obviously, that was mandated by the Act, but it was also a very wise thing. We mailed it out to more than 30,000 grocery stores across the country, and if ever there was an act that was consistent with what the philosophy of this administration of the Environmental Protection Agency is, that is the public's right to know. We have, over the last four or five years, reached out to the public on every major issue we're tackling.

We realize that none of these laws can be implemented without partnerships with people like each and every one of you in the room, partnerships with the general public. We have not reached Nirvana, but we have gotten better at involving the public in one issue after the next, in assuring that stakeholders, people who have an impact from the industry side to the state government side and local government to the environmental community side, that they are involved in our decisions, in our regulations, in our practices and, again, I believe we are a smarter and more thoughtful agency because of those partnerships and that involvement. The community right-to-know spirit of this administration has moved us further in taking on our responsibilities and carrying them out well.

I think this Act is a perfect example of an Act that will not be successfully implemented without the involvement of partners from state government, to local government, food agencies, agricultural agencies, chemical companies, and environmental groups. Today is a very big part of bringing thoughtful, key stakeholders into the process and making sure we're looking at some of these issues together and proceeding in a way that makes sense. So with this Act we continue one of the most admirable things of this administration, and that is involving the public; community right-to-know

pieces, and 30,000 grocery stores hopefully are now helping move that new information out to the public.

Pesticide concerns that have been in the news recently are striking at everybody. As we reach the tenth anniversary of the Alar apple crisis, Consumer's Union and the Environmental Working Group have both recently published their concerns about pesticide residues on fresh fruits and vegetables. We may feel things have gotten better; they're not as convinced and we've got to work with them to make sure that we share their concerns about ensuring the safety of our children's food. We share every bit of their concern. It is our job to regulate pesticide use so that everyone's food is safe and we're going to work with them.

A year from now or two years from now, we hope to be seeing fewer scathing attacks on the pesticides that are out there on our food, and more cooperative relationships on how to regulate them, and how to do it in a way that works for all parties.

In almost every speech I've given since I've joined the Environmental Protection agency, and that's three years or so, there's almost always a reason to refer to my children. They're on my mind all the time, as is the case with any parent, and I could think of nothing that is more important to me than to make sure that food I'm putting on the table is safe. I'm fairly tough on my kids to keep up their quota of five fruits and vegetables a day. We all read about five fruits and vegetables a day; it's important to start them young. I've got a four year-old daughter and an eight-and-a-half year-old son and they know the drill is, five fruits and vegetables a day, one way or the other, even if it's three small oranges at 8:00 at night.

It doesn't help when there are mitigating articles that we're all reading that say, don't have your kids eating strawberries; or blueberries are toxic. Not everybody should be forced to go to very high-priced, Bread and Circus-kind of stores, a perfectly lovely store in my neighborhood where I can scream to my husband, make sure you buy organic vegetables and fruits for the kids. We shouldn't have to do that. Every parent, every person, should be able to have the confidence and the certainty, when they are forcing their kids to eat those five fruits and vegetables a day, that those fruits and vegetables are going to be safe. I could not be more passionate about that. I'm sure each and every person in this room cannot be more passionate about it and the public cannot be more passionate about it.

It is our job to get it right, to figure out how to do it, which I'll talk about briefly, and some far-smarter scientists and experts will talk about it following me. It's not going to be easy. The science in doing this is complicated. People think that these answers come easily overnight. Tomorrow we're going to make everything safe for everybody who's putting fruits and vegetables and other food on the table for their families. It's not that easy. On the other hand, it is important and I am

convinced that we're going to find a way to deal with it and make sure that dangerous levels of pesticides are not on our tables. We now have to figure out how to make sure we get there efficiently, expeditiously, with as much involvement of all stakeholders as possible.

But it is clearly why I'm particularly glad to see the Food Quality Protection Act, to see that it was passed unanimously by the Congress in 1996. It brings with extra clout the support I think it's going to take, that we're going to need to move it forward. It represents a big step forward in how we are required to regulate pesticides. It will make a difference in people's everyday lives. They will understand it, they will get it, they'll not sit and wonder about all this stuff the Environmental Protection Agency does. But as I said, it's a very big challenge for us scientifically. This stuff is not easy. I don't need to tell you that. You're living it; you implement and work on complicated scientific issues every day.

Let me note some of the main points of the Food Quality Protection Act. Pesticide residues are now regulated by a single standard for both raw and processed foods. EPA is required to weigh all routes of exposure to a pesticide, both the aggregate risk and multi-media, not just the exposure from one particular use. In addition, if groups of chemicals are thought to act by a common mechanism of toxicity, the risk must be weighed across the entire spectrum, the cumulative risk. We are not only looking at separate pieces. The Act also demands special protection for children, including an extra ten-fold safety factor in some cases, and it calls for a new screening program for endocrine-disrupting effects. We'll talk more about all of those things today.

These changes are clearly a big step forward for the safety of our food supply. At the same time, they create major challenges for us at the Agency, for other regulatory agencies, for pesticide experts and users, and public interest groups. Today I hope we start taking on those challenges, to learn about current issues related to our new pesticide law. Not that EPA's pesticide stewardship programs are solely centered on the Food Quality Protection Act. Let me at least note for context some of the other things that we're doing and I think carrying out well in the Agency. For instance, the Agency expects to finalize its pesticide and groundwater rule to assure that groundwater resources are protected from pesticide contamination. We are working on this area throughout our program offices. EPA has also established a pesticide urban initiative to address problems of misuse of pesticides within urban communities. I want to note that we unquestionably have taken the urban environmental problems, and moved them up as high priorities, given the vast amounts of pollution, the amounts of pesticide problems that exist in our urban communities. Another mark of what I believe is a philosophical change all in the absolutely right direction.

The EPA has established a Biopesticides and Pollution Prevention Division dedicated to reducing the use and risk of pesticide products. The EPA-New England Office's Pesticide Environmental Stewardship Regional Grant program, supports research on sensibly reducing pesticide use in New

England. Through the Massachusetts Integrated Pest Management "Partners with Nature" IPM Certification program, homeowner pesticide education programs in Vermont, and research into alternative methods of controlling blueberry maggots in Maine are going forward and are prospering because of money we've been able to bring to those states.

There's a lot of information to throw at you today and as the day goes on you'll be getting more and more thrown at you. I want to make sure that we all learn today. Let me just take one more minute and boil down some of the bottom-line themes of EPA's pesticide programs because they are themes that I think form the basis for all of our work here today as well as all of our work at EPA New England. One is a real focus on the most vulnerable sections of our populations, whether it is children exposed to pesticides, asthmatics exposed to air pollution, or elderly and others with compromised immune systems exposed to poor quality drinking water. EPA is committed to extending to all people the right to not be exposed to dangerous levels of pollution.

We are making special efforts to reach out to those communities of people who have not gotten enough of what they need to bring them back into society in a way that's comfortable so that they're not suffering special ills. We haven't fixed those problems. Asthma's still rising. But we are dedicated to making a better effort and taking greater steps to deal with vulnerable sections of our population. Another theme is a growing methodology of not examining pollution problems, pollutant by pollutant or media by media, but instead looking at the whole of the problem. That is happening with pesticides through the Food Quality Protection Act and for other pollutants through EPA's multi-media approach. The problems aren't only in the water or just in the air or solid waste; they're cumulative.

We can no longer afford to look at these things on a piecemeal approach and we're not, and I think we will get to far better and smarter solutions for the problems because of that approach. This approach, though, requires a renewed emphasis on strong science for good decision making. EPA is constantly struggling to improve the scientific basis for our decisions to ensure that we really are doing everything we need to do to protect ourselves. We don't want to study things to death. We don't want there to be ten-year studies on every chemical. On the other hand, this is complicated stuff. People will be fighting us every step of the way. Our science need to be strong, needs to be good, and we're going to make sure we do that. And right along with this holistic approach comes an emphasis on pollution prevention rather than cleaning up after the fact.

Looking for ways to use less toxic chemicals in manufacturing is really the only way to go, and to use fewer pesticides in growing our food. We've seen tremendous reductions in toxic use emissions and we expect to see this trend continue. It doesn't happen accidentally. It takes partnerships, it takes aggressive programs, it takes resources from the federal government. We are aggressively trying to bring as many of those resources into the region as possible to share with all of you and we

will keep working at it.

And the final theme that I see happening at EPA is a commitment to increased cooperation between EPA, the regulated community, environmentalists and the public. And once again, that is why we're here today, to cooperate with each other, to learn from each other, to work together to make the regulation and use of pesticides in this country more successful.

Let me say one more thing, and that is these laws, the laws that we have all worked on collectively, whether they're the Safe Drinking Water Act, the Superfund laws, the air pollution laws that we are acting under, they have made a difference. It has been a long struggle. It has been 20 years in some cases, two or three years in other cases, but let me just cite one or two facts that are heartening to me.
In the days when we are pushing through two years of study on one small issue, to really step back and think that collectively we have made an enormous difference, not only in the environment, but in people's lives, and I believe this Act gives us another ideal opportunity to continue that kind of string of success. Because of the Safe Drinking Water Amendments of 1996, I believe, 86% of the American population will receive drinking water that meets all health-based standards in effect since 1994. The quality of the drinking water has been brought up enormously. 585 Superfund toxic waste sites have been cleaned up as of the end of 1998, and an additional 85 construction completions will occur in 1999. 227 communities have benefited from grants to revitalize urban brownfields, leveraging over $1 billion in private investments. Thanks to the passage of the Clean Air Act, approximately 164 million Americans are breathing cleaner air today. I could go on and on. My key point is, this stuff works. We passed these laws. When we get to the business of implementing them with partnerships, with lots of thought, with good science, and going at it the way we did with a number of the other things I've just mentioned, we will meet with success. I look forward to the work of today that's getting us to the next step in our work here in the region in implementing this law and to continuing to work with you on a regular basis for the future. Thanks very much and have a good day.

Koethe
Thank you, Mindy, for helping put this meeting in the context of EPA priorities. Our first speaker to discuss implementation of the Food Quality Protection Act is Jim Jones. Jim is currently Director of the Registration Division in the Office of Pesticide Programs (OPP). Prior to that he served briefly as an Associate Director of the Field and External Affairs Division in the Office of Pesticide Programs, and as Chief of the Registration Support branch in OPP. Jim's been with EPA for 11 years. He has a master's degree in economics from the University of California at Santa Barbara and a bachelor's in economics from the University of Maryland at College Park. Jim will provide an update of the Food Quality Protection Act.

Implementation of FQPA From A Tolerance Reassessment and Registration Perspective

James Jones

Good morning. It's good to be here in New England. I actually don't get up here professionally too often as the Director of the Registration Division; however, I hail somewhat from this region. I grew up in Albany, New York and I have family all throughout Massachusetts -- New Hampshire as well. So I get up here personally quite a bit. Not too much on business, although I have been waiting quite some time for Jerry Downing to invite me to some of his cranberry bogs. Maybe this will be the opportunity to get such an invitation.

This morning I'm going to give a broad overview about how we at EPA and the Pesticide Program are implementing the Food Quality Protection Act, both from a tolerance reassessment perspective and a registration perspective. Mindy gave us a nice overview of what the Act did in terms of changing our statutory requirements in the pesticides program. That includes going to a risk-only standard, and a requirement that we add aggregate risks across all sources of pesticides exposure as well as accumulated risks where the pesticides share a common mechanism of toxicity. That new standard needs to be applied to both old pesticides -- that's the program that the statute refers to as tolerance reassessment; that is, tolerances that were on the books before the law passed in August of 1996. The law also requires that the new standard be applied to all new pesticides, both new active ingredients for registration as well as new uses of old active ingredients. That latter part, registration, is the area that I work in. However, I'm going to cover both areas here this morning.

The tolerance reassessment program, which requires all existing pesticide residue tolerances, all 9,000 tolerances that were on the books at the date of passage of the Act, be reassessed against the new safety standard in a 10 year period. The first third of those need to be reassessed by August 3, 1999, a few short months from now. The EPA is confident that we will meet the goal of reassessing one third of the tolerances that were on the books when the statute passed. We've reassessed about 2,300 now and we think we'll have another 1,000 done before August 3rd.

Soon after the law passed, the Agency established a Tolerance Reassessment Advisory Committee. It was clear from the get-go that there was going to be a lot of controversy involved in implementing the statute, in particular the tolerance reassessment aspects of the statute. The EPA senior management, and I'm referring to the Administrator level, as well as the USDA senior management level, the Secretary's office, decided that we should have an advisory board which is composed of about 45 stakeholders. It includes a very wide and diverse group of individuals representing growers, manufacturers, public interest community, states and others, and has been meeting over the last year and a half. Its purpose is to give the Agency advice about how to go through the reassessment process, focusing largely on the organophosphates which is one of the biggest classes of pesticides that we'll be looking at and one of the more controversial ones.

I think the Agency feels that we have gotten two fundamentally solid pieces of advice that we have acted on where we felt the Advisory Committee was telling us something that we really needed to do. I'll spend a little time talking about those two things that we have begun to do. Some of them are pretty far along. They both have to do with some of the things that Mindy was referring to earlier. Basically, having a process that's much more transparent. Having more stakeholder involvement in our process, which in the pesticide program frankly has not been our strength.

We may be one of the later programs to have gotten on board with some of the right-to-know issues that the Administration has been focusing on over the last several years. But the TRAC, the Tolerance Reassessment Advisory Committee, suggested there were two areas which we really needed to cover. One was that there were clearly major science policy issues that we're going to need to meet before we can go forward with any reassessment. I'll touch a little on some of those this morning. And secondly, they recommended we have a far more public process for announcing the risk assessments that we complete.

We have had some experience with making public our risk assessments in the Pesticides Program but historically we have not had a very public process for the outcome of that, the regulatory management that comes at the end of that. If it's not acceptable, what uses are we going to mitigate or potentially drop to get the risk to where it needs to be to meet the standard? So, we have both those recommendations we have followed through with.

We've identified a total of 19 science policy issues, and the TRAC was very active in identifying these 19. It started out as nine and as people kept thinking about them and talking about them, more got added and we've gotten to 19 right now and I'm not saying that we're not going to have any more, but right now there have been 19 identified. On all of these 19 we have issued, or we will soon issue, Federal Register Notices. We've been posting our interim operating policy on them on our web site. And we're taking public comment on our policy. After we have considered the public comments, we will issue a final policy.

Some of these issues are going to be very familiar to many of you, as we've been talking about them since the day the law was passed. Verse one is, how will EPA implement the extra ten times safety factor for infants and children? That's one that's gotten a lot of attention over the last several years.

Another one that we've heard a lot from the users about is, how does EPA interpret the risk when there are no detectable residues on a crop where there's been monitoring involved? EPA has historically used half the limit of detection, or half the limit of quantification for that. There's been a lot of criticism of that policy, so we have issued a notice that identifies how we're actually going to be doing it, and we're taking public comment on that.

How will EPA calculate drinking water exposures? We've got to aggregate exposures across all sources. You can be exposed to pesticides through your food, you can be exposed in your home, you can be exposed at school, and you can be exposed through drinking water. OPP did not assess aggregate drinking water risks prior to FQPA; it's very new for us. We have been working on it for the last three years. We have struggled with it, and we have now published a notice that describes how we're doing it, and we're taking public comment on that.

Another one that's just specific to the organophosphates (OP's) is, what is the appropriate toxicological end-point for assessing the OP's? There has been a lot of controversy about that -- it's an issue that we've taken to our Science Advisory Board three or four times over the last five years. Some people say you should only be looking at cholinesterase inhibition in the brain; some say it is in the blood, that's what's biologically important; others say it's in the plasma. We've currently taken a weight of the evidence approach, and that's what's in our current policy.

Another area we're taking public comment on is, when does a food use not require a tolerance? To give you an example, you can be applying a pesticide to a fruit tree during dormancy. That would seem to be a food use, you're applying a pesticide on a tree that bears food. However, it is certainly possible that there will be no residues on the fruit. We have historically established tolerances for those situations, and this policy describes a proposal for not even having a tolerance for such a situation as that.

Another one that's been very controversial is, what's the appropriate percentile of acute dietary exposure at which EPA should be regulating? Since prior to FQPA, we have very refined data that has been used in a probabilistic risk assessment, also known as Monte Carlo. We have regulated at the 99.9th percentile of exposure, which to some seems like we're over-regulating, and to others it seems like we're under-regulating. If you're talking about a population of several hundred million, which we are, that 99.9th percentile, leaves a rather large theoretical number of people above that level. It's been very controversial, so we've decided we would take public comment on that. This is one of the science policy issues we have not yet released for comment. I think that one's going to be issued in the next 30 days.

The last one that I'll briefly mention, I'm only mentioning about 10 of these as opposed to the whole list of 19, is how should EPA use Pesticide Data Program data? This is the data the USDA collects; it's monitoring data. It's a program that was created several years ago, whereby the USDA goes out into commercial warehouses, collects samples of food items, and measures actual residues. If you're talking about a pesticide that's got chronic concerns, we have had no problem using the Pesticide Data Program data. One of the details of PDP is, they will take a sample of 10 bananas, and they'll take the 10 bananas and they'll mix them all up. And if we're talking about a chronic risk, on average an individual is being exposed to something chronically, will get basically

the mush in the 10 bananas. And that's a not inappropriate scientific judgment for us to use. But for an acute exposure, where it's the consumption of one food item, and not a mix of five or 10 mixed together, it may be completely invalid to use a blender mix of 10 food items, and assume that an individual is exposed to one. You could have wide variance in what went into that mix. You could have something that had 100 parts of per million, and the rest of them had zero parts per million, and the average therefore is going to be 10. But that's not what that person ate who had the banana with 100 parts per million on it. And so, we've been struggling with it and we think we've come up with a creative solution for how we can use PDP data for acute dietary exposure and we're articulating that in a notice which is going to be issued in April of this year. We haven't completely dismissed PDP data for acute dietary exposure, which is very important for the OP's and the end-point is acute risk. We have come up with somewhat of a solution for how we can use that data.

Those are 11 or so of the science policy issues that we have or are about to issue notices on asking for public comment. They're available on the Internet. Many of the people here from EPA could direct you on how to get access to those if you haven't already.

One of the things we're struggling with is that we've gone to such a degree of transparency and there is so much for people to participate in, that groups, even organized trade groups or public interest groups, let alone individuals, are having a hard time handling the volume of information. At the same time we feel that we need to move forward to meet some of the statutory time frames.

Those science policy issues, with the exception of one or two, are very generic science policy issues, and the way in which they are resolved over the next several months will likely apply to all tolerance reassessments, not just the OP's, as well as to registration activities.

I'm going to talk briefly now about where we are with respect to the OP's. The organophosphates were identified as one of the high priority classes of chemicals that the Agency would review first in its tolerance reassessment efforts. Although it is unlikely we will have reassessed all of the OP's by the August 3, 1999 deadline, we will meet that deadline, and there will be many OP's that will be included in that deadline, including about nine of them which have already been voluntarily cancelled. Most of the nine that have been voluntarily cancelled had very few food uses though. Again, we're trying to have a very open, transparent process for our work on the organophosphates.

We've developed a six-phase process that has multiple opportunities for public participation. The six phases are as follows: In the first phase, the registrant, the manufacturer of that particular organophosphate and the Department of Agriculture get 30 days to correct any errors that they may think are in our preliminary risk assessment. Currently we have 10 OP's that are just about

ready for phase one.

In phase two, EPA considers comments that USDA and the manufacturers have made; there are currently two OP's in that phase.

In phase three, the preliminary risk assessment is made available to the public through the Federal Register as well as through our Internet site. 13 OP's are currently in phase three, their preliminary risk assessments are available for public comment, and the comment periods have not closed yet. We are generally providing 60 days of public comment on our preliminary risk assessments.

In phase four, EPA refines its risk assessment and David Miller, who will be speaking after me, will be talking this morning, about what is entailed in defining our risk assessment. In phase four, that's what we do, we get in there and we refine the risk assessment, incorporating comments that we received in the public comment process. There are currently 14 OP's in phase four, in which we are refining our risk assessment.

In phase five, EPA releases the refined risk assessment and begins to accept comments on regulatory management options. If the risk is acceptable for the pesticide, there may be very few relevant regulatory options. If the risk is not acceptable for the OP, there is going to be a need for some mitigation. It is at this stage that we're going to be asking the public to give us options for mitigating risks. I think this will be a very relevant time for growers and manufacturers, as well as for the public interest community. This is where changing use patterns could be considered.

We've certainly had a lot of experience in pesticide regulation where changing the use pattern can take a pesticide that may have been used heavily at the end of the season, if used earlier in the season can significantly change the risk attributable to that commodity. This will be where that kind of mitigation will be considered. This is the part of the process where growers try to identify lower benefits and higher benefits uses. Clearly, if we find ourselves in the position of dropping uses of pesticides, which is a very likely outcome, our objective is going to be maintaining the uses with the highest benefits and the lowest risk and dropping those with the lowest benefits and the highest risks. That will basically be the philosophy that we use. The public's participation is very valuable. You know, as growers, which of these compounds provide the highest benefits to you, which provide the lowest benefits, which have alternatives, which have no alternatives, when use patterns are practical to change; all of this will be considered.

It's very likely at that point that the EPA and USDA will actually meet with specific grower groups and with manufacturers individually to more intensively discuss risk mitigation. For example, if one crop seems to be accounting for 80% of the risk, the logical thing could be to work with that one crop to see what we can do to get that risk down significantly. That may make the overall risk OK

for another 15 or 16 crops that that chemical is used on. Those meetings, however, will be docketed, minutes will be taken and they'll be put in our public docket so that there will not be any closed-door sessions in which the public does not have the ability to know what kind of a deal got cut behind closed doors.

Finally, in phase six, EPA will develop risk-management strategies and ultimately make risk-management decisions. So that's the six-phase process that we have identified for the OP's. It's a pilot process; if we are successful in using this process for the OP's, it will likely be considered for other chemicals in tolerance reassessment. As I mentioned, 12 OP's are in the first period right now, two are with USDA and the registrants to correct any errors we may have made, and on 10 we are about to issue a preliminary risk assessment.

Now I'll talk briefly about registration basically of synthetic, not antimicrobial, pesticides, which is the area that I work in. Registration has a critical role in the tolerance reassessment process. To the extent that the Agency is removing pesticide uses or pesticides from the market, the availability of alternatives becomes even more critical than it was in the past, so we have taken some steps to acknowledge our importance in that process.

Last year we registered 13 new conventional active ingredients and 73 conventional new pesticide uses. This year we plan to register 13 new active ingredients and another 75 new uses. Although we're at about the mid-point in our fiscal year, and for the first time since I've been managing a production-oriented regulatory program in OPP, at mid-year we're actually revising our estimates upward. We think we may be able to register 15 new active ingredients and upwards of 100 new uses this year.

We've made reduced-risk pesticides our top priority. Last spring we made the registration of OP alternatives another very high priority, right up there with reduced-risk pesticides -- and methyl bromide alternatives, of which we have not seen very many. This year we expect to register six organophosphate alternatives. For the first time, we are going to be publishing our annual plan of work for new chemicals and new uses, somewhat of a controversial action on our part that wasn't widely embraced at the beginning. Actually, growers have always thought this was a great idea. The work plan was just signed, and will be in the Federal Register and on our web page next week. The work plan identifies all the new chemicals that are proposed for registration, the crops they'll be registered on, the manufacturer, and the time of year in which we plan to make the registration decision, as well as any special characteristics, such as, is it an OP alternative or is it a reduced risk pesticide? We hope that by doing so, we will allow the users to have greater access to what's going on in the registration program. Researchers are finding this very useful as they can identify compounds that may not have been proposed for the crop that they are interested in for registration, but knowing about it, they can do things to affect that. They can work with the

registrant, they can work with IR4. We have had growers who have felt that if they had access to what was coming down the pipeline, they'd be in a much better position to be aggressive with manufacturers and with EPA about pursuing new uses. I'm also looking for greater accountability on my part as well by doing this.

The Section 18 program is another area that I know growers are very concerned about, and I think there is a higher degree of confidence that we've been able to turn Section 18s around in the manner that the user community had become accustomed to prior to FQPA. Last year we averaged a 53-day turnaround time; this year I think we're going to beat our 50-day goal, so we're very pleased with that.

In summary, I think that we have embarked on a rather bold, new course. Not only do we have a statute that is dramatically different that we are working very hard to implement, but we have opened up the process in the Office of Pesticide Programs at EPA in a way more dramatic than ever before. We're very hopeful that by having a more open and transparent process, we will not only make better decisions, but those decisions will be better understood. Thank you.

ROBERT KOETHE: We have time for one question now. Bill?

WILLIAM COLI: Can you explain how the risk assessment process you described is going to be completed by August, given the statement you made about the policy issues being decided upon before the risk assessment process can even go forward?

JONES: I think that it's pretty clear that for the organophosphates, it's highly unlikely if not impossible to complete the final risk assessments and final regulatory management before August 3, 1999. We're not even going to be issuing our final guidance on how to do the cumulative piece until December of this year. So, although we are quite confident we will meet the statutory goal of having 30% of all tolerances reassessed by August 3, 1999, we will not complete the reassessment of all the OP's. There are several OP tolerances that we will be able to count as completed. For example, if a manufacturer voluntarily cancels one, we can count it. One of the other science policy areas we're thinking about is called Early Winners. These are use patterns that pose so low a risk, that we might as well just say we're done. They are going to stay. Those can be counted as well. So, some OP's will be counted by August 3, but the vast majority of them will not be.

Data Needs and Risk Assessment

David Miller

Koethe:

I'd like to introduce David Miller who has been with the Health Effects Division for six years, working as a residue chemist and risk assessor. The focus of his current work at EPA is probabilistic risk assessments. Prior to his agency employment he was a sanitary engineer in the Peace Corps, assigned to the Ecuadorian Ministry of Public Health. He was also an associate engineer at a health and environmental sciences consulting firm in Arlington, Virginia. He received his bachelor's degree from the University of Pennsylvania and master's of science and master's of public health degrees from Virginia Tech and the University of Michigan, respectively. He's a commissioned officer in the U.S. Public Health Service. Mr. Miller will speak to us about data needs and risk assessments under the Food Quality Protection Act. David.

David:

Hi. My name's David Miller. I'm a residue chemist and exposure assessor in EPA's Office of Pesticide Programs in Washington, and I'm going to talk to you today about risk data needs and assessment.

The next slide please. I'd like to provide an overview of the talk. I'll start with an introduction to the Food Quality Protection Act and touch on some of the science impacts of the Act. One of the major science impacts is aggregate exposure; I'll talk a little bit about that. Considering aggregate exposure is a new requirement under the Act and it has had a major effect on what we do. I'll then go into the risk equation. When the Agency says a risk exceeds or doesn't exceed a level of concern, this is the equation we use to make that determination. It has two parts: the first part listed there is the hazard identification and dose response part of the equation; that's in essence the toxicology part. And that determines the size of the risk cup, if you're familiar with that terminology. The other aspect is the exposure part; it's how much is in the risk cup. There are two parts to that: one is the residue chemistry part, how much is in the food; and the other is food consumption, how much of that food you eat. With that as a background, I'll talk a little bit about the DEEM software; DEEM stands for Dietary Exposure Evaluation Model, and that's what we use to perform our risk assessments. The output is, in essence, a risk. It's not necessarily our best estimate of the risk; we can always go back and refine it, and produce better risks if we get better information. That will close out my morning discussion. Then this afternoon, in the breakout groups I'll talk about these additional two topics: the tiered approach to risk assessment -- when we refine our risk assessment we have a tiered approach, starting with the worst case and going to more and more refined

estimates; and then, finally, risk refinement -- that will include some options for the kinds of data that we'd like to see, or believe could help our risk assessment process.

The next slide. This is a brief overview of the Food Quality Protection Act; it amends FIFRA and FFDCA, the two federal laws that are concerned with pesticide residues in food and pesticide uses. It was enacted into law August 3rd, 1996. It was in force immediately, which meant we had to hit the ground running; there was no lead time or preparation time, and everything we did as of that date had to comply with all the requirements of the Act. Another thing that was mentioned before is it requires that 9,000 tolerances be reassessed over the next 10 years.

Next slide. Here is a list of some of the major science impacts of the Act. Some of them have been mentioned before. I'll just briefly go over them. One is the additional ten-fold safety factor to account for the special sensitivity of infants and children. The second is the development of testing and screening methodologies for endocrine disrupters, which is scheduled to be discussed this afternoon. There's also aggregate exposure; the EPA under FQPA is required to aggregate exposures across pathways. Before FQPA, we looked at food alone and residential exposure alone; we didn't combine the two. Now, we have to look at food, we have to look at water and we have to look at residential; and also look for the potential co-occurrence of these exposures. Before it was separate, and now we have to consider them, in addition to separately, but together as well. Finally there's the requirement under the Act that we do cumulative exposure across chemicals. So, if chemicals have a similar mechanism of toxicity, before FQPA we were doing one chemical at a time; now if there are similar mechanisms of toxicity we'll have to combine those risk assessments. In the illustration in the next slide is a chart summarizing the aggregate exposure and the kinds of pathway exposures we look at. Pre-FQPA, we looked at dietary or food separately from residential, separately from water. They weren't combined. Prior to FQPA, we did not generally look at drinking water except under special circumstances. Post-FQPA, we're required to continue to look at drinking water, residential and occupational separately. We're required to add in drinking water and we're also required to combine, in an aggregate exposure, drinking water, food and residential exposures. Taking into account potential co-occurrences -- you can be exposed on the same day to food with pesticide residues, to water, and use pesticides in your home, for example. The talk will concentrate on the food portion of the assessment, but remember that well have to do the aggregate with drinking water and residential exposure as well.

This next slide shows the risk equation; in other words, how do we calculate that the risk of pesticide X is unacceptable, but the risk for pesticide Y is acceptable. We use the risk equation to do that. It's equal to exposure divided by hazard. The hazard part is the toxicology part of the assessment and consists of a reference dose. I'll talk more about the reference dose in a minute, but in essence it's the maximum safe dose that one should be exposed to, expressed in milligrams of pesticide per kilogram of body weight per day. The exposure part is the second part of the risk

equation. It consists of pesticide residues in food and food consumption.

In the next slide I give a specific example of how the calculation is done. Risk is expressed as a percent of the RFD, or percent of the safe dose. It's equal to the exposure divided by the reference dose. The reference dose is determined from toxicological studies which I'll go into in a little bit. The reference dose is essentially the size of the risk cup. The exposure is how much is in the risk cup and the risk, as a percent of the RFD, or percent of the safe dose, is how full the risk cup is. For example, if the exposure was five and the RFD was 10, you'd say the risk cup was half full, or 50% of the RFD was occupied. If the exposure, on the other hand, was 10, the safe dose and the RFD was 5, you could say the risk cup was overflowing, or 200% of the RFD had been occupied. Remember that exposure is calculated from two things; it's calculated from pesticide residues and from food consumption together. And the RFD is determined from toxicology studies.

Next slide. Now that we have the basic equation, it's applied to two different kinds of risk assessments. The first is chronic, which is long-term exposure; and acute, which is short-term exposure. Long-term exposure is generally considered over a year to a lifetime. For those risk assessments we use average residues and average consumption. The acute is short-term, generally a day, a spike for example. For acute exposure, we use either high-end residues if the risk assessment is less refined, or we use probabilistic methods if it ends up being more refined. That's the entire range of residues used. On the next slide I'll go into some of the specifics of the risk equation. It's the hazard identification dose response; it's the toxicology part of the risk equation. And again, this measures the size of the risk cup. We use toxicology studies.

Next slide. We use a number of toxicology studies done on laboratory animals to determine the size of the risk cup; that's the acute RFD, the maximum safe dose. The toxicology studies are used to determine toxicity endpoints and their associated doses. What's done in the laboratory studies is a series of doses. For the acute, a series of single doses is given to the animals, maybe on 50 animals, five different doses. And the toxicity endpoint is looked for. In this case, for acute it might be the inhibition of an important enzyme. The associated dose with that in this case might be .4 milligrams per kilogram of body weight. That would be called the lowest observed effect level. To determine chronic toxicity, it's a similar kind of study, except instead of a single dose it's giving repeated doses over the course of several years or the lifetime of a rat. Toxicity endpoint would generally be something different. In this case it might be the proliferation of liver cells and the associated dose that causes that. The lowest dose that that effect is seen at might be for example .2 milligrams per kilogram of body weight per day. Those endpoints and the doses associated with those endpoints are then used to calculate the reference dose. That's the maximum safe dose you can be exposed to. We don't use those, the .2 or the .4; those are the lowest effect level. We go down to the no-observed effect level, which is one level lower. It may be the range that was given in the dosages was from .1 to 1 part per million; the lowest dose where an effect was seen was

maybe .4; you'd go down to the next lower one, and that would be the no-observed adverse effect level. And then you'd divide that by the applied safety factor; generally they range from 100 to 1,000. In this case, if the dose at which an effect was seen was .4, the next lowest dose at which no effect was seen was .2; that would be the no-observed effect level. We divide that by a factor, generally 100 to 1,000, and in this case .002 milligrams per kilogram body weight would be the RFD. That is what we determined to be the maximum safe dose, and that is the size of the risk cup. Every use, every exposure then, has to be added to the risk cup and has to fit into that. The exposure is not allowed to exceed that level. On the next slide I talk about the required toxicity studies. This is a list of the various studies we require. There is acute and chronic, and sub-chronic in there as well. These are the kinds of information that are submitted to the Agency by the registrants that we review and use to determine what the safe doses are; the reference dose or the size of the risk cup.

Next slide. Once you know the size of the risk cup, the next question is, how much is in the risk cup? There are two factors: one is the pesticide residue or pesticide concentration in the food that's eaten. And the other is how much food is eaten. Together those determine how much pesticide you're exposed to. In these next couple of slides I'll cover how the Agency decides how much pesticide residue is in the food we eat. That's the residue chemistry part, which is shown here. Generally, there are two key residue chemistry considerations which we look at, and which the registrants submit data on. The two key questions are: what chemical is there, and how much is there? The what is there is determined by the nature of the residue study, also termed a metabolism study; that's done with both plants and animals. It determines essentially what compounds are there that we have toxicological concern for. You may, for example, apply pesticide X. It may have breakdown product Y; it's quite conceivable that the breakdown product is just as toxic or more toxic than the parent chemical. These methods essentially indicate what chemicals are there that are of concern. The purpose of these studies is to identify what's there, not necessarily quantify what's there. The how much is there, the quantification of what's there is done in a separate kind of study; again, these are done by the registrants and submitted to the Agency for review. Those are called magnitude of the residue studies. There are two kinds: one is done with plants, and those are the crop field trials that the registrants perform; the other is done with animals, for meat and milk, for example, and those are termed animal feeding studies. I'll just go through the plant example here. This answers the "how much is there?" question. These are the steps, the criteria that we would use in evaluating a study. The manufacturer is required to apply the pesticide at the maximum label rate and harvest at the minimum post-harvest interval. The main purpose of these crop field trials is to determine how much pesticide residue potentially could be there. We know typical rates are a lot lower; we know typical post-harvest intervals are a lot higher, but the purpose of this is to determine a tolerance. The number of trials we require depends on where the crop is grown. They range from three to about 20. Kiwi fruit, for example, might require three trials all in California, whereas corn would require 20 field trials throughout much of the Midwest. Trials have to be

geographically representative of where the crop is grown as well. For example, if 60% of the potatoes are grown in the Pacific Northwest, that's where 60% of the field trials would have to be done. And finally, the crops are analyzed by the registrant for compounds of toxicological concern. It's not necessarily only the pesticide chemical; we may have identified breakdown products which are of toxicological concern that would have to be analyzed as well. So that's where the "what" is. Part of the question is answered by the metabolism study.

Next slide. The second part of that is determining the exposure; that is, how much is in risk cup? It is consumption data; so consumption data times the concentration would give you the exposure data. This is the second half of the risk equation -- how much food is consumed? The consumption data is part of the DEEM software which we use; again, it stands for the Dietary Exposure Evaluation Model. The consumption data from there is derived from USDA's continuing survey, food intake of individuals. They conducted it in 1989 and 1991 and did it again in '94- '96 and I think they're planning on doing another round in 2000-2002. They statistically sample people around the country; a total of 10,000 people for three days, asking them to write down everything they eat. So you end up with 30,000 people-days of information. Again, those are real dietary data. And that's the baseline of our assumption for consumption data, the 30,000 person-days. That's what we use to calculate what their exposures are when we do the risk assessment. It takes into account such differences as age, sex, ethnicity and race, season, region of the country, etc. So that's where the consumption part of the data comes from. I'll talk a little bit about the DEEM software. What that does is it combines all the information that we've received from consumption and exposure and the RFD together and prints out a risk. The inputs to the DEEM software combine all the information we know together in a proper manner. One input is toxicity information in the RFD; that's derived from toxicity studies as I indicated before. You look at the toxicity endpoint and apply a certain number of safety factors. The RFD, you remember, is the maximum safe dose, which tells you how big the risk cup is. Exposure information is the second part of this input; it could include the crop field trial residues which I described to you before, but it also could include a number of refinements. For example, we could insert USDA's pesticide data program data, if were doing a chronic assessment. We could incorporate processing factors if we know when foods are processed, corn into corn oil, for example; if we know that that's reduced by a factor of 100-fold in the deodorization process, we could incorporate that. Percent of crop treated could be incorporated as well. The output from the DEEM software is the exposure level, a distribution of exposure levels. It's given in milligrams of pesticide per kilogram of body weight per day. And that tells you how much is in the risk cup. It also includes the risk which is expressed as a percent of the reference dose, or percent of the maximum safe dose, or equivalently how full the risk cup is. So that's the output that we use in our risk assessments. If the exposure exceeds the safe dose, we use a tiered approach to refine the crop field trial residue inputs.

The next slide shows the conclusions. These are the first two conclusions; the latter two will be

covered this afternoon when I go through the tiered approach that we use, as well as some of the residue refinements that we could use to refine our risk assessments. The two basic conclusions are: FQPA has had major impacts in the way exposures are assessed and risks are calculated at the Agency, requiring us to aggregate exposures and look for the probabilities of potential co-occurrences from residential, drinking water and dietary sources. The second main key point is, risk is calculated from an equation which combines toxicity information and exposure information. Exposure information is derived from pesticide residue levels in food and the amounts of these foods consumed.

Are there are any questions? I'll go through the tiered approach as well as risk refinements at the sessions this afternoon. Yes, go ahead.

JOANNE CUMMINGS: What do you do if pesticide residues are found which are above the tolerance level, or a residue is found from a pesticide that is not authorized for use on the food being analyzed?

MILLER: Those would be considered illegal uses. That's an enforcement issue. PDP collects data, FDA collects data for enforcement purposes, and if there are flags on that -- if they detect a crop has higher residues than the allowable tolerance, for example, that would signal them that there is an application or illegal use problem and the FDA would cover that. So, at this point, no, we don't look at illegal uses. The gentleman in the beard.

MAN: Do you consider the effect of pesticide residues on birds or animals other than humans?

MILLER: The ecological effects are done in a different division. I'm not very familiar with what they do; they have their own toxicity criteria. They're more concerned with ecotoxicity and the health of populations of organisms, rather than human health, which is the concern of the Health Effects Division -- the toxicology to individual organisms instead of populations of organisms. So, no, they're different. Go ahead.

MAN: Why do you use a factor of 100 as opposed to another factor?

MILLER: Why 100 as opposed to another factor?

MILLER: Originally 100 was the default. 10X was for interspecies; between rats and humans. The other 10 to make 100 was for sensitivities within the human population -- the expected potential sensitivities on an order of magnitude. So, 10 times 10 would be 100. As part of FQPA, there was concern that there may be infants and children who have special sensitivities that weren't accounted for by that 100-fold factor. And so what FQPA required was that, unless registrants

submitted data which showed that infants and children were not more susceptible, you'd essentially incorporate it up to another 10; so the default is 1,000. If they submit information that indicates that infants and children are not more susceptible, then we can go back to 100. But again, that needs to be something that the registrants submit; otherwise it's 1,000.

MAN: What do you do when illegal pesticide residues are found on the sampled food?

MILLER: As far as enforcement goes, that's FDA's responsibility. The EPA doesn't enforce the residue tolerances; it's the FDA that sends out the inspectors and will seize the crop if it's been illegally treated. In general, it's something like if they find 1% of the crops has illegal residues. Most of it is not because residues are over tolerance; most of it is it's present but not registered for use on that crop. It could easily have gotten co-mingled with other crops that ended up being treated. Oversprays and things like that. So, in general, I'm not sure but it's something like on the order of 1%; so it's a small percentage that they find. And a lot of it probably isn't misapplication, a lot of it might be overspray, for example, from other farmers or intermingling from other crops. There are generally very low levels.

MODERATOR: How about one more question before the break, and then again, after the panel there will be another chance to ask questions.

MILLER: OK, go ahead.

WOMAN: Can you clarify how the DEEM software works?

MILLER: What the software will do, it can do either a point estimate or a probabilistic estimate. Let me just talk about probabilistically. You have the 30,000 person-days of food consumption there. What it will do is assign a residue to each; if somebody ate an apple, corn and a banana, for example it will assign a residue to each of those. So that person's total exposure would be calculated. And it ends up being ranked; you would pick an exposure at a high-end level, for example, at this point at 99.9. We have real diets and what we do is plug in residue concentrations from field trials as a first cut, from moderating data if that's available. Incorporating things like percent of crop treated, and processing factors. And for each individual person, each individual real diet, we look at what the exposure is. And then compare that to the maximum safe dose. So it's for the 30,000 diets that we look at.

Panel Discussion

Moderator - Andrew Triolo: I would like to start the panel presentations by introducing Rob Koethe, who is responsible for setting up the meeting. Rob is the regional pesticide expert in the EPA-New England Office. In that role, he provides technical support and guidance to the New England State pesticide regulatory programs. He also advises the educational, scientific and industrial communities and the general public on various pesticide issues. Prior to coming to work for EPA, Rob worked for eight years as the Integrated Pest Management advisor with the University of Illinois Cooperative Extension Service. Rob has a B.A. in biology from Gettysburg College, an MS from Penn State University, and his Ph.D. from North Carolina State University. Rob will be our lead-off speaker, and we'd like to have each of the speakers take about 15 minutes for their presentation, and save the bulk of the time for questions and answers. And at the question and answer period, I would ask that the morning speakers join the panelists on the dais. Rob?

KOETHE:
The panel is composed of representatives from several different parts of EPA and other agencies that have different perspectives on food quality protection, and we all have different roles in the implementation of FQPA. EPA Region 1 works with the six New England states, and EPA has 10 regional offices around the country. While each of the regional offices have their own priorities, whether it be helping implement the Food Quality Protection Act, or other areas, the regional offices share certain core responsibilities to work with state programs and implement federal environmental laws.

This presentation starts with a brief description of how the Region 1 Pesticide Program operates. I'll give an overview of some of the important pesticide issues and highlight some of the Food Quality Protection Act activities that we are involved in, and then finish up with some comments on activities that we plan to conduct in the future.

For each of the EPA programs we have responsibilities to ensure that federal environmental statutes are implemented. In the case of the Pesticide Program, we work closely with our state partners. For pesticides, we have cooperative agreements with the states, and the states have primary responsibility for enforcing pesticide use laws, and certification and training of pesticide applicators. In Region I we need to identify our priorities very carefully; our two main priorities are to support the state programs and to support regional and headquarters' initiatives.
We're fortunate that in New England the state programs are strong, and all New England State programs have laws that are stricter in some areas than the federal laws are. For example, all New England states have some type of lawn care posting and/or notification law. New England states also required special permits for certain pesticide applications.

Our second priority is to help implement headquarters' and regional initiatives. While these initiatives change over time, it seems to me that once an issue surfaces, such as worker protection, it never really

goes away, it just becomes part of the on-going activities, and a number of issues have been raised over the eight years that I've been with EPA. Some of the regional priorities we support are Indoor Air, the Urban Environmental Initiative, and the Children's Initiative, and we also work on tribal issues.

Our next slide shows an expanded list of some of the national priorities that are also very important to the region. Especially important, in addition to the Food Quality Protection Act, are groundwater protection, which Mindy noted this morning, integrated pest management, the Pesticide Environmental Stewardship Program, and certification and training of pesticide applicators. I'd like to make few comments about groundwater protection.

Several years ago EPA proposed a rule to protect groundwater resources from contamination by those pesticides which have been shown to be the greatest threats. The final rule is expected any time now. This law is a little different than the Food Quality Protection Act in that it is aimed to protect groundwater as a resource so, it's aimed at public health but it's also aimed toward environmental protection.

Other priorities of the regional office are integrated pest management and the Pesticide Environmental Stewardship Program. These are non-regulatory programs but they're important to us because they contribute to reduced pesticide use and risks to people and the environment. USDA Extension Service has developed strong Integrated Pest Management (IPM) programs for many crops. EPA support has been especially strong for IPM in non-agricultural areas, especially urban areas.

I'd like to make a few comments about the Pesticide Environmental Stewardship Program, which emphasizes reduced risk and reduced use of pesticides. In Region 1 we've been able to support a number of research projects through grants from the PESP program, and some of them were mentioned by Mindy earlier today. The Vermont Dealer Education Program; an investigation of alternative methods and reduced-risk management methods for controlling the blueberry maggot in Maine on low-bush blueberries; a review of parts of the Massachusetts Partners with Nature Program, kind of an assessment; and support for biological control in greenhouses.

Now I'll discuss what we're doing about the Food Quality Protection Act, which is the next slide. The Food Quality Protection Act is a good example of a high priority national program, and also is very important here in Region 1. Some of the efforts that we have done to get the word out on food quality protection are: distribution of materials; ever since the law was passed in 1996, we've been sharing fact sheets and the information that's developed to our partners and the public. We respond to special requests for additional information on the Food Quality Protection Act. In 1998 we had a meeting between Lynn Goldman, former Assistant Administrator for Pesticides and Toxic Substances, and a group of New England stakeholders.

Looking at each of these areas in a little more detail, distribution of materials. Here are some of the materials that are available. A lot of this information is also available on the Office of Pesticide Program's Internet site. Just so you have an idea what some of these things look like, in your packet you have a copy of a "For-Your-Information" fact sheet on FQPA, which gives a very good overview of the Act.

There is information available from the Tolerance Reassessment Advisory Committee, and the schedule that you have has been shared with that group. The TRAC material is also available on the Internet.

The most recent piece of outreach information that we've distributed is the Consumers Pesticides and Food Right-to-Know brochure, which is also in your packet. Generally, we first share the materials we have with the pesticide state lead agencies, and then the cooperative extension, and, finally we respond to requests for information. Because we work most closely with the state pesticide regulatory agencies and Cooperative Extension, we get a large number of requests from them, but we also get requests from other parties including the regulated community, public interest groups and the public. An especially interesting request was from the New Hampshire legislative committee on agriculture and the environment. When the FQPA law first came out, the committee was trying to get a better handle on what its impact would be on the states. The New Hampshire Division of Pesticide Control and then the regional office staff briefed the committee; that was followed by a briefing by Dan Barollo, the former director of the Office of Pesticide Programs.

We held a meeting with Lynn Goldman last spring, and my estimate was there were about 30 people present at that meeting. They represented many of New England's major commodities including cranberries, blueberries, small fruits and vegetables, and potatoes. There were also people present from EPA Region 1, state programs, state departments of agriculture, universities, public interest groups, and the pesticide industry. Some of the issues that were raised at that meeting were some of the ones that are part of the program today. Most of the time was spent talking about data needs and assessment, and the sense that I got when the meeting began was that some of the people present were skeptical about how serious EPA really was about getting additional information, so there were a lot of logistical questions. Lynn Goldman agreed that this is an area that will need additional follow-up. Risk issues were another area of discussion at that meeting, and there was some discussion about the assumptions for field sampling data. And of course, a lot of this was in the context of the organophosphate insecticides, because it was known that they are among the first pesticides to be reviewed, and there have been rumors that they would be canceled. Dr. Goldman assured the group that there was no intention to completely eliminate OP's. She also emphasized the importance of the Tolerance Reassessment Advisory Committee, and that committee has really grown in importance. At that meeting it was decided we ought to have some type of follow-up, and this conference today is part of our follow-up.

We assembled a planning committee, which included representatives from all the state lead agencies and the cooperative extension services, and we looked at the issues that were raised at our roundtable meeting. We also scanned the newspapers to get some insight on what FQPA issues are most important to people. We also decided that some type of interchange with the stakeholders would be important.
The way this conference is laid out is that after our panel discussion there will be a good amount of time for questions and answers. In the afternoon we expect there to be a lot of focused discussion on the session topics. If you have questions or points that you'd like to raise with some of the speakers this morning, please do so. All of the speakers will be around until the end of the meeting with the exception of Jim Jones, who has to leave after lunch. So, try to catch up with the people that you need to talk to.

Finally, as follow-up to this meeting, we plan to write up the proceedings and we'll get that information out to you with as many of the support documents as we can. We're going to include a summary of the meeting that we had with Lynn Goldman last year in the proceedings. The proceedings will provide a snapshot of where we are with regard to Food Quality Protection Act at this point.

In the regional office, we plan to expand our outreach. We're hoping to reach more audiences and partners on pesticide and food safety issues, and also on the Food Quality Protection Act. Some of the other panelists will discuss something called the Agricultural Initiative, which was started along with the Food Quality Protection Act a couple of years ago. At present this program is a pilot but there are rumors that the program will be expanded to include all 10 regions. Last year there were four regions that were selected for pilot programs, including Region 4, Atlanta; Region 5, Chicago; Region 9, San Francisco; and Region 10, Seattle. Those regions received some support from headquarters, including a full time position and grant money, and they have been able to do a lot of great things relative to the Food Quality Protection Act. Again we're hoping the program will be expanded to include all 10 regions.

We try to stay active in IPM and the Pesticide and Environmental Stewardship Program, and we do our best to make sure that these things complement each other. I already mentioned that we expect to expand our outreach as much as we can. We're going to make greater use of the pesticide page on the Region 1 web site, and when we get the proceedings completed from this conference, we'll have that available there; we're also going to improve our links with some of the resources that are available at headquarters.

MODERATOR: Thank you, Rob. Our next panelist to speak is Lora Lee Schroeder. Lora is the Food Quality Protection Act specialist in the Region 4 office. Ms. Schroeder has held this position since 1998. Prior to accepting her position with EPA, she was the Pesticide Division Director of the Georgia Department of Agriculture. She was in that position for six years, and before that she was the

Pesticide Branch Director. Ms. Schroeder has also served as Agricultural Manager of the Georgia Department of Agriculture. She holds a B. A. in English from Berry College, a B.S.A. in Horticulture from the University of Georgia, and an M.P.P.M. in Plant Production and Plants Management from the University of Georgia. Ms. Schroeder...

SCHROEDER: One thing you didn't mention, which I'd like to share with you, is I represented the state pesticide control officials on the Tolerance Reassessment Advisory Committee, had the opportunity to hear many of their discussions and provided input into some of the science policy issues. I served on Work Group Number One, which dealt with a number of the science policy issues. I'm new to EPA. I bring to it some perspective from the pesticide control officials and the agricultural community. I worked very closely over the years on processing Section 18's and approving pesticide registrations, and also have had the opportunity to direct the structural pesticide control program in the state of Georgia. While we haven't heard a whole lot about indoor residential exposure, that is one of the elements of the Food Quality Protection Act, so hopefully that experience will help me as we move closer to implementation. I asked, when I came on board, what do you want me to do, and they said, well, what do you think we should do? So, I came up with my own agenda.

One of the first activities I was involved in has to do with communication; you're dealing with some very complex issues, and you have to communicate this to a public who doesn't have time to sit at a computer all day and search the Internet for this information. So, one of my first tasks was to come up with a means of communicating information about the Food Quality Protection Act to the general public. And my idea of doing that was to develop an information update newsletter, which I've done and have published a couple of editions. I have copies of that which I brought with me that will be available to all of you. Some people have asked me how I came up with the name; it's called Alphabet Soup. Now the reason for Alphabet Soup is, we're dealing with 24(c)'s and Section 18's and FIFRA, and FQPA, and all kinds of acronyms, and that's the genesis for Alphabet Soup. The newsletter discusses some of the good activities that are going on in the region, the grant programs that we have and how we're working with those individuals in our state. We'll have at least one article that will discuss some of the more progressive activities that are going on. We have a program in the Mississippi Delta with the cotton farmers where they're promoting best management practices.

In addition to developing Alphabet Soup, we've been giving a lot of presentations. I've met with the commercial applicators of Georgia, and had an opportunity last week to talk to a very large group of commercial pesticide applicators. We had 15 remote stations for that presentation, so a large number of commercial applicators were able to take advantage of the presentations that were given. Though I think a lot of us here have heard a lot about FQPA, there are many people out in the field who really don't have a clue as to what it is all about. So, one of my goals is to try to get information out and as far down as possible. We've talked to professional crop management associations; we've talked to the national Pesticide Information Retrieval System.

Since I've been on board I've met with NASDA, the National Association of State Departments of Agriculture; I had an opportunity to work with those folks over the past couple of years in developing pesticide regulation policy for that group. A lot of the work dealt with the Food Quality Protection Act and associated issues. Agriculture Commissioners are a very important group of people to inform about FQPA.

We have an Agriculture Initiative grant that is specifically related to FQPA. EPA has a lot of other grant activities that may be targeted at pollution prevention and other areas, and I'm trying to coordinate our activities with other programs like the Water Program. I'm looking for sources of funding that will meet our goals as well as their goals. One of the first things I worked on was the Sustainable Development Challenge Grants, where we were looking at a lot of community activities. We had some proposals from that group which dealt with pollution prevention and agricultural activities, such as organic production and preservation of greenspace, and we put forward two which had strong agricultural pesticide components. We have several on-going projects under the Agriculture Initiative, and of course I'm working very closely with those individuals. I think sometimes we fund a project and then we kind of forget about it, and don't get the information out as rapidly as we could. There are some really good things that are coming out of these various projects, which I want to share with other regions and groups that are interested in these products. At the meeting with Imperis in Hilton Head last week, I was able to show an excellent video that was developed by our Mississippi project on the cotton stewardship activities that they're doing. It was very well received.

Of course, a lot of what we do in the regional office is traditional enforcement type activities, and I think you've already heard about what's happening with traditional activities in Region 1. We haven't gotten into the enforcement aspect of FQPA yet, but as decisions start being made concerning labeling changes and risk mitigation measures, the regions will have to make sure that the label provisions are abided by. There will be responsibilities for us to educate those who are used to using pesticides in a certain way that they need to start using them in another fashion.

Another thing we're doing is providing feedback to headquarters. Regions have a much closer relationship with the state pesticide control officials, with the farmers, with the various ag organizations than does EPA headquarters, and we're able to bring information from those groups and pass it back up to headquarters. We do get questions about what's happening with the peanut farmers in North Carolina. What pesticides are of concern to them. What alternatives might they have. And we're able to respond to those questions and put the people in touch with the right group.

I work on various committees, I think one might be interesting to you. In Region 4 we have the Pesticide Environmental Stewardship Committee, which has individuals on it representing organizations outside of EPA, for example in the chemical industry, the extension service, and medical persons, and we're looking at developing an award that will recognize outstanding stewardship activities in Region 4.

We feel there are a lot of good things going on out there that farmers and others are doing, and I think it's important to recognize and encourage those efforts that are taking place in our regions, and to help promote even more of that type of activity.

I'm also spending a fair amount of time training our own staff. We have 15 project officers and program specialists who haven't had an opportunity to spend a lot of time understanding what FQPA is all about. Part of my task is educating our folks and making sure that they understand the importance of this piece of legislation, and what their roles ultimately will be.

We traditionally have had a very close working relationship with the State Pesticide Control Officials in Region 4. Also we've had a very close relationship with the Extension Service and meet periodically with those individuals. I have passed a lot of information to state agencies that we have received from headquarters and some information that I have developed myself on a fairly regular basis.

I think one of the things that's happening with FQPA is we have so much information that's coming at us, people don't know when important deadlines are being reached and don't know what the opportunities are for input. So, I'm trying to make sure that people are informed early enough so they'll have an opportunity to provide input. Thank you.

MODERATOR: Thank you Lora Lee. Our next panelist is Paula Fairfield. Paula is with the New England district of the Food and Drug Administration. As a supervisor of the Public Affairs office, she's responsible for managing the educational and outreach programs. Paula also oversees the activities of several staff including the Consumer Complaint Coordinator. Ms. Fairfield has held her current position for 15 years. Prior to that she was an investigator for six years. Ms. Fairfield is a member of the Association of Food and Drug Officials of Rhode Island, and she is currently treasurer of the Northeast Food and Drug Officials Association. She has received numerous awards including the National Performance Review Hammer Award and the FDA's Outstanding Achievement Award. Ms. Fairfield holds a BS in Education from Framingham State University. Ms. Fairfield.

FAIRFIELD: Good morning. Listening to Alphabet Soup and the need for education on the Food Quality Protection Act reminds me that when Allan Christensen called me and asked me to be on this panel, I said, Food Quality Protection Act? Now, that should have something to do with what the FDA does. Well, in looking it up I found that yes it does have something to do with what we do in FDA, however, it's main impact has been on the EPA.

FDA is responsible for enforcing the Federal Food Drug and Cosmetic Act and FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act. The Food Quality Protection Act amends those two laws. The greatest impact on the consumer is that there is supposed to be a more plentiful and a safer food supply by allowing newer and more effective pesticides on the market.

As was the case before the passage of this law, EPA is responsible for registering pesticides and for setting residue tolerance levels in food. And FDA enforces the tolerance levels established by EPA. The law did give enhanced enforcement power to FDA in that it allows the imposition of civil penalties; fines of up to $500,000. The act removes pesticide residues in processed foods from the definition of food additives which is how FDA regulated them. And therefore from the restriction of the Delaney Clause which said that if an additive caused cancer in man or animals, it could not be used in the food supply. The revised measure of safety of pesticide residues in processed food and raw food is one in a million over a lifetime.

The FDA is charged with enforcing tolerances in imported foods as well as in domestically produced foods shipped in interstate commerce. USDA's Food Safety and Inspection Service monitors the pesticides residues in meat and poultry and in certain egg products. FDA acquires incident data on particular commodity pesticide combinations and we carry out a market basket survey each year to look at these levels. This is called the total diet survey. And since 1991 USDA's Agricultural Marketing Service has carried out a residue testing program on raw agricultural products and various processed foods.

There are a lot of people looking at the pesticides in the food supply. FDA samples individual lots of domestically produced and imported foods and analyses them for pesticide residues to enforce the tolerances. Domestic samples are collected as closely as possible to the point of production in the distribution system. Import samples are collected at the point of entry into U.S. commerce. Emphasis is on raw agricultural product which is analyzed as the unwashed, unpeeled raw commodity. Processed foods are also included. If residues are present which are above EPA tolerances, or if there is no tolerance for a particular pesticide on that food combination and these are found in domestic samples, FDA can invoke various sanctions such as seizure and injunction, and we now have the ability to assess civil penalties. For imports, shipments may be stopped at the point of entry when illegal residues are found. Detention without physical examination is what we now call it. It was previously called automatic detention. That may be invoked for imports based on the finding of one violative shipment if there is reason to believe that the same situation will exist in future lots during the same shipping season for a specific shipper, grower, geographic area or country.

Domestic and import food samples collected are classified as either surveillance or compliance samples. Most of the samples collected by FDA are the surveillance type; that is, there is no prior knowledge or evidence that a specific food shipment contains illegal pesticide residues. Compliance samples are taken in follow up to the finding of an illegal residue or when other evidence indicates that a pesticide residue problem may exist.

Factors considered by FDA in planning the types and numbers of samples to collect include: a review of recently generated FDA residue data; regional intelligence on pesticide use; the dietary importance of

the food; information on the amount of the domestic food that enters into state commerce and the amount of imported food that arrives at the ports of entry; chemical characteristics and toxicity of the pesticide; and pesticide usage programs. To analyze the large number of samples on which pesticide treatment history is usually unknown, FDA uses analytical methods capable of simultaneously measuring a number of pesticide residues. These multi-residue methods can determine the amount of residue of about half of the approximately 400 pesticides with EPA tolerances and many others with no tolerances. The most commonly used multi-residue methods can also detect many metabolites, impurities and alterations of products of pesticides. Single residue methods or selective multi-residue methods are used to determine pesticide residues in foods. A single residue method usually determines one pesticide whereas a multi-residue method measures a relatively small number of chemically related pesticides. The single residue method is usually more resource intensive.

Personnel in FDA's field offices interact with their counterparts in the states to increase FDA's effectiveness in residue monitoring. In many cases we have memoranda of understanding or more formal partnership agreements that have been established between FDA and various state agencies. These agreements provide for more effective monitoring of the pesticide residues by broadening coverage and eliminating duplication of effort, thereby maximizing federal and state resources allocated to pesticide activities. These arrangements vary from data sharing, joint planning and state collection of samples for FDA examination, to FDA and state division of collection, analytical and enforcement follow up responsibilities, for the individual commodities or products of particular origin. That is, imported versus domestic products.

We also participate in several international agreements in an effort to minimize incidents involving violative residues and trade barriers. A standing request exists for information from foreign governments on pesticide use on their food exported to the U.S. This is a provision of the Pesticide Monitoring Improvement Act. Under the auspices of the North American Free Trade Agreement, the United States, Mexico and Canada have established a technical working group on pesticides which serves as the focal point for all pesticide issues that arise among the three NAFTA countries. One of the working group's major goals is to ensure that pesticide registration and maximum residue tolerances in the three countries are harmonized to the extent practical while strengthening protection of public health and the environment.

FDA's Total Diet Study is the other element of our pesticide residue monitoring program. In conducting the study, FDA personnel purchase foods from supermarkets or grocery stores four times a year, once from each of four geographic regions of the country. The 261 foods that comprise each market basket sample represent over 3,500 different foods reported in USDA's consumption surveys. These foods represent what an average family of four would normally eat within a week's period of time. The foods are prepared table ready and then analyzed for pesticide residues as well as radionucleides, industrial chemicals, toxic elements, trace and macro elements, vitamins B and folic

acid. The levels of pesticides are used in conjunction with the USDA food consumption data to estimate dietary intakes of the pesticide residues.

In 1997, 9,843 samples of which 9,652 were surveillance and 191 were compliance were analyzed for regulatory monitoring purposes. Of these, 4,501 were domestic and 5,342 were imports. You can find the results of those on FDA's home page on the web. If anyone is interested I can give you the address a little later. I'm just going to give you a brief summary of the results. As in earlier years, fruits and vegetables accounted for the largest proportion of the commodities analyzed. Those two commodity groups comprised 65% of the total number of domestic surveillance samples. And in 1997, no violative residues were found in 98.8% of all domestic surveillance samples. Overall, no violative residues were found in 98.4% of the import surveillance samples. This figure in 1996 was 97.4 and in 1995 it was 96.8%. You can see the figures are following a downward trend.

An adjunct survey of baby food that has been done from 1991 through to the present has only found evidence of small amounts of pesticide residues in those foods and those levels also have been going down. In summary, a total of 9,843 samples of domestically produced food and imported foods from 97 countries were analyzed for pesticide residues in 1997. Of these 9,652 were surveillance. Again, these are collected when we have found no evidence of a problem. No residues were found in 66% of both the domestic and the imported surveillance samples. The higher violation rates in the 191 compliance samples reflect the fact that they are collected and analyzed when a pesticide problem is suspected.

FDA also collected and analyzed animal feed samples of which 460 were domestic and 42 were imports. 62% of the domestic samples and over 52% of the import surveillance samples contained no residues. Most of the Total Diet Study findings for '97 were generally similar to those found from earlier periods and, again, they were going down.

I would like to mention the good agricultural practices that FDA has published in the Federal Register in conjunction with the USDA. These are guidelines for farmers to assure that their produce is as safe as possible. In addition to dealing with pesticide usage they deal with sanitation practices on the farm.

We have been finding that as the problems with pesticides have been decreasing, the problems with the microbes in the food supply are increasing dramatically. A few years ago we never heard of cyclospora in raspberries. We thought they were perfectly safe to eat. Now there are questions about them. The microbe issue is really the bigger issue that FDA is involved with at this point in time. Our pesticide activities are going down because we've been finding less and less residue in the food supply and our activities as far as the microbes are concerned are increasing.

We have finalized HASSOP regulations for the seafood industry. We've published proposed

HASSOP regulations for the fresh fruit juice industry. And the trend seems to be going towards HASSOP for the food industry, and probably for the farmer at some point in time in the future. Thank you.

MODERATOR: Thank you Miss Fairfield. Our next panelist is Evelyn Washington. Evelyn is the Associate Chief of the Targeting and Analysis branch in the EPA's Office of Groundwater and Drinking Water. Her branch is responsible for the development of regulatory tools such as cost-benefit analyses, contaminant candidate lists, national contaminant occurrence databases and lists of treatment technologies, as well as development of individual contaminant regulations such as those for arsenic and radon. Prior to becoming the Associate Chief, Evelyn served as team leader for the Contaminant Identification and Selection Team that developed the drinking water contaminant candidate list. Miss Washington is a chemical engineer by training and began her career at EPA in 1988. She received her bachelor's degree in chemical engineering from the University of Maryland at College Park. Prior to working for EPA, Ms. Washington worked for the United States Department of the Navy. Ms. Washington.

WASHINGTON: I'm going to start out by confessing that I'm not an expert on FQPA. The term risk manager applies to the type of work that I do. I'm in the drinking water program. We have had some involvement with FQPA related to drinking water, and in terms of risk management we rely on the risk assessors or the toxicologists who develop the reference doses. We take that information and develop the regulations which public water systems have to comply with.

The topics I'm going to go over today are: highlight some of the main points of FQPA, talk about the Safe Drinking Water Act, and then get into some of the common elements in both. The common elements and the need for both programs, the pesticides and the drinking water program, to get data from one another requires us to improve our coordination between the two offices, so I'll spend some time on that as well.

I came to the drinking water program in 1991. When I arrived there I was surprised to find that the drinking water program did not have what we call an occurrence database. There is no one place that we can go to in our program to look at concentrations of any contaminant in drinking water. We do have a database that is related to compliance. It's related to whether a public water system violates a monitoring requirement or violates a maximum contamination level (MCL). In the case when an MCL or standard is violated the public water system through the state reports concentrations to the agency.

There's no one database where just routine monitoring and parametric data is reported to us. But that's going to change. We are in the process of building what's called a National Contaminant Occurrence database. That's going to be on-line by August of '99. At that time, public water systems will have to monitor for contaminants that are regulated, contaminants that have standards, as well as other

contaminants that the agency specifies and has to report to a central database whether the concentrations are below or above the MCL. We're moving in the direction of building such a database to support the program. And so the reasoning behind the fact that a database never existed, back in the late >80s, we were spending a lot of time regulating contaminants that Congress said you shall regulate. There were about 150 contaminants, so it didn't matter whether they occurred or not in public water systems, we had to set standards.

The emphasis of the program now is going towards more of a risk assessment and risk-based standard approach, and again, we need the data to do that and are building the database. A lot of people call us and ask us what contaminants we are finding in drinking water, and we've never been able to answer that at this point.

Concerning FQPA, I'm not going to go into a lot of the details. I think Mindy and David who presented earlier went through a lot of that, but I want to point out I think there are three key components that you'll see as a reoccurring theme, not in the Safe Drinking Water Act, but in our improved coordination effort. One deals with this whole concept of risk assessment where we look at aggregate risk; where we try to use the best science available to assess those risks. The second element is special consideration for infants and children. And we'll talk about that a little bit later. And the other component that I want to point out is this right to know aspect of FQPA. The Safe Drinking Water Act amendments of '96 were passed about three days after FQPA was passed, and those amendments require us to put greater emphasis on our assessments, that is, our assessments in terms of risk as well as our cost-benefit analyses that we have to do. So, stronger approaches in preventing contamination deal with source water protection issues. Wellhead protection as well as watershed protection issues are made stronger by these amendments. The Safe Drinking Water Act requires public water systems to report to consumers the status of how well the water systems met the MCLs or the standards, and some description of what that means so consumers can understand what the risks are that are associated with drinking water. That is comparable to the FQPA brochure that was put out regarding pesticides in food.

Regulatory improvements in terms of better science, prioritization and improved risk assessment were part of the Safe Drinking Water Act. I mentioned additional cost-benefit analysis that we have to do, provisions where we do a lot more peer review than we did. We use the best available science in our assessments. We go through a process of prioritization, so that we identify contaminants that we feel are the highest priorities in terms of requiring future regulations or revisions to current regulations.

The last two elements are a state drinking water revolving fund -- this is a pot of money that can be made available to states and public water systems through grant mechanisms to help the smaller public water systems comply with the regulations. There are additional Agency provisions which meet the needs of smaller public water systems requiring greater flexibility in terms of compliance and so forth,

but I think the drinking water state revolving fund is the biggest element related to small systems.

Next slide. In terms of common elements, pesticides and degradation, in the drinking water program we deal with not only pesticides and degradation products, we deal with the microorganisms, we deal with disinfection byproducts, other synthetic organic contaminants and inorganic contaminants as well as radionucleides and those compounds. So, the pesticide component of what we do is just a piece of the pie for us. The use of the best available science is a common theme through both Acts. In the Safe Drinking Water Act, we are mandated to consider sensitive sub-populations when we do a risk assessment and it specifically identifies infants and children as a sensitive group, but it also mentions elderly immuno-compromise. So, again, there's a common theme there.

I mentioned the consumer confidence reports and these reports that public water systems have to include in the water bill. And then there is the endocrine disruptors issue. Both statutes mention testing and screening for endocrine disruptors, and there's a program in the agency called the Endocrine Disruption Testing and Screening Advisory Committee, EDTSAC. That committee is working from the language in the Safe Drinking Water Act as well as FQPA to develop a testing and screening program that the Agency can use to analyze endocrine disrupting compounds, or contaminants considered to cause endocrine disruption.

Another element that I didn't include up there is public participation. Within the Safe Drinking Water Act there are a number of elements which encourage a greater level of public participation than previously required. We have to provide an opportunity for public comment on assessments that feed into regulatory development before we get to the proposal stage. When we do a proposal, we'll publish it in the Federal Register, take public comment on it and then do a final rule. We have an added step where we have to do a Health Risk Reduction and Cost Analysis. We publish in the Federal Register for comment at least six months in advance of a proposal, and then put out the proposed rule again, seek comment on it, and then develop the final rule.

In an effort to meet our public participation elements, we've held a number of stakeholder meetings on various topics that relate to developing drinking water standards. We've discussed everything from how we're starting to do our cost-benefit analysis and the changes we're making there to how we're identifying priority contaminants. The drinking water program needs some assistance in terms of data to support the drinking water portion of this aggregate analysis, because we should be the people that have that data. We have the authority in the Safe Drinking Water Act to require public water systems to submit that data to us. So, we can use that provision to get what we need and also to get the Office of Pesticides what it needs in order to complete its assessments.

The other aspect of that is, in developing drinking water standards we rely on a lot of the same health effects information that the Office of Pesticides has a really good handle on. So, again, another swap of

data would be appropriate to help us do what we need to do. A group of us got together and started to look at how we could improve the coordination between the two programs, and we identified a number of goals that we would like to achieve from this improved coordination. I've listed most of them there. Some of them I've already dealt with. For instance, we use common methodologies when we do our risk assessments. When we look at data concerning the hazards of particular pesticides or degradation products, or when we look at occurrence data we should come to the same conclusions. So, if you called up the folks in the drinking water program and asked what's your estimate of the risk of pesticide X and then you called up the pesticide folks and asked the same question that you'd get the same answer. We also thought it would be good to have common priorities in terms of which contaminants we regulate, and also contaminants that require monitoring by public water systems.

In the area of science policy, some of those issues are fundamental to the way you would do risk assessment. This last one relates directly to the risk cup scenario. In the case when you're dealing with an overflowing risk cup, we need a joint coordinated policy about how we're going to deal with it. We've come up with some basic agreements that have been fed through the management process. The first one goes a long way in creating a common human health risk assessment methodology. When the Office of Pesticides does its hazard assessments that we use the assessments that the Office of Pesticide has come up with. That we play in those work groups, that we play in the science policy issues, and then when it comes down to having the final assessment, we take that into our program to help us develop our drinking water standards.

In the discussion about common approaches to risk assessment, the particular issue that I'm getting to here is the Ten X factor that's added on for addressing children's and infant's risk when there's uncertainty. We're not sure in the drinking water program whether that's appropriate. So, by talking about common approaches to risk assessment, if we find that there are situations where we won't be doing the same thing, we need to articulate why we won't be doing the same thing. Sharing data on pesticide occurrence is important. This has been a major effort with the development of the National Occurrence Database. We have made sure that the Office of Pesticide Program folks that deal with the data systems are considered one of the major users of our occurrence database. We're going to be requiring public water systems to monitor for certain contaminants on the drinking water contaminant list. In developing that list we involved folks from the Office of Pesticides to give us an assessment of the likelihood of some of these contaminants appearing in drinking water, based on physical chemical properties and modeling estimates. I think I mentioned the cross program involvement in science policy earlier. The biggest element in this whole area of coordination is how we deal with the concept of the overflowing risk cup.

In this work group we feel that the risk cup is the main issue that we need to get to. The other underlying components get us to this main issue. If we agree that the risk assessments are done and then come to the point where we look at the risk cup when you've included exposure from food,

exposure from water, exposure from residential use, and you have a cup overflowing what do we do? Do we change the drinking water standard, or do we clamp down on some of the uses? I'm not sure we'll come up with a canned answer. I think it might be pesticide specific, but we'll see how it goes. And this is going to be one of the breakout session topics that we'll talk about this afternoon.

The last element is the ecological risk assessment. In the Office of Water there is a component of our office called the Office of Science and Technology that deals with developing water quality standards. These are ecologically based standards and in some of our discussions with the Office of Pesticides, we determined there may be a need to also look at common methods for assessing ecological risk. We also put out in the Office of Water fish advisories where, if certain contaminants are found in fish above certain levels, we issue advisories warning consumers about consuming those fish. This whole area of fish consumption and fish advisories and fish action levels is something that's come up in the discussion between the two programs. One concern is that when we look at aggregate exposure, there are populations who consume fish at higher rates than the general population. How do we account for that in these risk assessments that we do?

In terms of priorities among all of these things, getting to this issue about the risk cup is the highest priority of all. We've taken these through our management all the way through the Administrative Deputy level. We have a steering committee, which has been in existence since October of last year. We are in the process of developing options that'll identify the nuts and bolts of how we're going to make these agreements work and presenting those options to management for decisions. This is something that is of great interest to both the Office of Water and the Office of Pesticide programs. Our Deputy Administrator, Dana Minerva and Susan Wayland, the administrator for the Office of Pesticide programs are both interested in what we're doing. We don't have a definite time frame laid out for all of this, but these are the steps that we plan on taking.

You have a sheet in your packet called getting information. It talks about the Office of Pesticide's program's web address. I want you to add the web address for the drinking water program. If you look at that sheet, there's a word there. The last word on the end of that line is pesticides. If you type in everything else and then in place of word pesticides type the word safe water as one word, S-A-F-E-WATER, it will take you to our Office of Groundwater and Drinking Water web site. We're also developing the occurrence database which we're going to make accessible through the internet. So, if people are looking for occurrence data on particular contaminants, eventually that will be the place to go once it's on-line.

MODERATOR: Thank you Evelyn. We've got about 10 or 15 minutes for questions. At this point I'd like to ask Dave Miller and Jim Jones if they would join the other panelists so that they can respond if any questions come up. OK. Yes, Bob.

MAN: I think there is a departmental misunderstanding of this whole thing. If the risk cup is a function of total points, water, food and residential, how can you assess a standard for any one of those if the total is going to be a function of what the other two are? We just heard a talk about water, and I'm thinking they can set a standard on our intake of it, but that allows the residue in water to be a function of what those other components are. And how do you say what's the limiting component? I guess I just don't understand that.

MODERATOR: Get Dave Miller to do this one.

MILLER: I think what you're getting at is, how do we do it when there's a source coming from food, a source coming from water and a source coming from residential, how do we combine those three? One thing we can't do is assume worst case food on top of worst case water on top of worst case residential, so what we're proposing is to do this assessment probabilistically. There's a paper on the web that was presented a week ago to the SAP. It's an issue paper on how we propose to do aggregation. If you go to the epa.gov/pesticides/TRAC web site, it shows up as whatever last Wednesday's date is, and that indicates what we intend to be doing in terms of the aggregate risk. What we propose to do is take into account the probabilities of the co-occurrence of somebody treating the lawn at the same time he gets a high dose from food at the same time he gets a high dose from water.

WOMAN: A separate side question is how do I find the paper on your web site?

MILLER: Actually you're right. It is the Scientific Advisory Panel, SAP. I was wrong. It's capital S, capital A, capital P. It has to be capitalized, and there will be a date. They list all the different dates, and it's last Wednesday's date when it was presented and the paper's there in Word Perfect and Adobe Acrobat and HTML format.

WASHINGTON: I want to add something I think might help, because it was hard for me to understand this when I first got into it. What we're comparing is a reference dose, which is the calculated health level. You're looking at the exposures that you get from the different sources.

MAN: You mean exposure from the different pathways.

WASHINGTON: Yes, exposure from the different pathways compared to that reference dose. You're looking at something you calculated versus what you're actually measuring. I think that's the intent of this risk cup scenario. The size of the cup is determined by the reference dose, and you're apportioning based on exposure; apportioning your reference dose based on what you measure in drinking water and what you measure from food consumption and what you're measuring from residential exposure. Whether you actually have measurements for all of those is another story. Does

that help? When we set our drinking water standards, we assume that 20% of the reference dose is the bottom line amount, the amount that one would consume through drinking water, unless we have other data. Most of the time it's the standard 20% because we've not had a lot of data and we haven't looked at the data that the Office of Pesticide Programs has. So, when we talk about risk cup at this afternoon session we'll get into some of these scenarios.

MODERATOR: OK. You're up.

MAN: Yes, I have a couple of questions that relate to risk assessment and how the FDA's role plays in all of this. Specifically, how does the information the FDA and USDA have developed in the real world historically over the years correlate with the field study data that's being used now? That's the first part of my question. The second part of my question is, what analysis is being given to the potential of the removal of pesticides increasing other risks to society? For example, if I lose an organophosphate that prevents insects from piercing the skins of my apples before harvest, and it's known that pierced skins at harvest will allow the E. coli in the insect inside of my apple, and the removal of organophosphates allows an increase in notable pierces in apples, and therefore a potential increase microbial contamination, is that risk measured?

JONES: Concerning the comparison between the crop field trials that are submitted by the registrants and the marketing data that we receive from FDA as well as from PDP, when we have the real world data that's what we prefer to use. We don't always have that. The crop field data studies were done to support tolerances which represent the maximum legal residue. So, in order to support that, those tolerances have to be done at the maximum rate and harvested at the minimum pre-harvest interval. Otherwise if they use typical rates or typical PHI's you'd end up with essentially illegal produce when the pesticide was used perfectly legally. We do use that information from PDP or FDA when it's appropriate, when it's available.

MILLER: To answer the second part of your question, the statute requires that the pesticides that they were looking at are safe, and it then defines safe as having a variety of characteristics. The use of that OP in this example has to be safe, has to meet the standard. The way we get to the point of determining which uses need to be modified or dropped if you do have a risk greater than acceptable and an overflowing risk cup would be incredibly important to ultimately making a determination. I think knowing that you may create a bigger problem on apples when such a problem would not exist if you were to remove the use on another crop would be very important in determining which one to keep. So, it would be used more in the risk management as opposed to any kind of risk assessment purpose.

MODERATOR: OK. Back there.

MAN: My concern is that FQPA may have a negative impact on pesticides in a whole bunch of

situations. When a particular pesticide has a broad spectrum of uses: in agriculture; smaller in structural pest control. Are you going to decide that the risk cup is full and it's use is in a high agricultural market, it sounds like it would force the manufacturers to eliminate this pesticide in the small special markets. Are there any considerations to review the pesticides on the whole spectrum of the market?

MILLER: Yes, again those kinds of considerations will be very important when you're trying to decide which uses should be maintained and which ones shouldn't. The benefits provided by structural pest control are clearly very significant and will be considered in the context of the risks that are posed through those uses as well as the risks and the benefits of other uses -- agricultural and lawn care uses. Although we're going to have a very open process in coming to a consensus about how to mitigate unacceptable risks, at the end of the day if the manufacturer's not going to support the use, the manufacturer's not going to support the use. But it's never been perfectly clear to me that their profit margins are highest on agricultural versus nonagricultural uses. I think that may vary depending on the company and the chemical. So, I'm not sure that they will all universally say we're going to get rid of this kind of use first.

MODERATOR: Joanne.

WOMAN: I have a question for Jim Jones. I don't mean to put you on the spot, but when you were saying in the registration process your highest priority is to try to find products that are less risky. Why should isoxyflutole be registered? Because in Vermont we probably never will allow that pesticide to be used, so why would that be registered?

JONES: Isoxyflutole or "Balance". I'm perfectly happy to answer that question -- it's not an FQPA issue. That's a chemical that's very persistent and mobile and although it's a low use rate herbicide, it's likely to leach at very low levels -- we're talking about in the parts per billion or parts for trillion even, get into ground and surface water, and it does have phytotoxicity issues associated with it. It was registered in parts of the United States that have certain characteristics. We basically determined that the benefits to the users exceeded the risks in certain parts of the country. It was not allowed in those states where there was very diverse agriculture and thus a possibility of the phytotoxicity issue becoming a problem. So, it was not allowed in the New England states. It was not allowed in any coastal state, East Coast or West or the Gulf Coast. It was basically allowed for use in the central part of the United States. Diverse agriculture and more diverse ecosystems were the criteria we used, and we felt that the risks exceeded the benefits in these more diverse agro-economic systems, and for the more monocultural areas we determined that the benefits of the use exceeded the risks, and thus it was registered there. It's not clear to me that we would ever register it in Vermont. One of the interesting aspects of this process is that for the states in which we proposed registration we asked all of them if they would see it differently. If they thought that in their state risks really did exceed the benefits. A

couple of states took a very hard look at that and ultimately decided to allow for the use in their state, but we made it pretty clear that if they felt that the risks of use in their state exceeded the benefits we'd very seriously consider that in prohibiting it in that state.

MODERATOR: Yes, right there.

MAN: Yes, mine is kind of a general comment to Ms. Lubber. She had mentioned in her talk that there were a lot of environmental statutes and that she is responsible for directing a staff of 800 people. I guess the thing that came to my mind is that here I am, part of a small farm community and being in this setting in Massachusetts, the adage came up where "once the embattled farmer stood". It's a big entourage of people, the small group of farmers is up against. Farmers consist of 2% of the population in this country; probably less than one tenth of 1% in New England. I wanted to make a comment that you can't close your minds to the intricate system that we have provided for safe food supplies for our country and for the rest of the world. In the things that are mentioned here today we have to work together and start the delicate process. I believe the EPA will do everything to protect itself. Paula Fairfield mentioned some of the programs FDA had in place today, including food monitoring for pesticides and other substances on food. And I guess the question that everybody here needs to understand with the Food Quality Protection Act is, when they open up this can of worms and I'm looking at the system we have in place, we growers will face more red tape and higher costs.

Marv Rosenstein: I'd like to respond to the gentleman who made the comments about food safety. The EPA and the government in general recognize that the U.S. food supply is the safest in the world. I think the Food Quality Protection Act is going to make our food safer without disrupting the very good infrastructure currently giving us our food supply. I think this is due to safeguards built into the legislation. So I think the EPA is going out of its way to open the dialog, to listen to farmers and the agricultural community. And I think the Act will make a good process even better without hurting anyone. The goal is not to get the small farmer, the big farmer, or anyone else.

Appendix I

Briefing on Endocrine Disruptors

LeBelle Hicks, Pesticide Toxicologist, Maine Board of Pesticide Control

Note: LeBelle volunteered to conduct this briefing when Dr. Chris DiFonzo was unable to come.

1. The function of the Endocrine System(s) is to allow the organism to deal with wide ranges of environmental conditions including exposure to chemicals (natural and man made).

2. Endocrine glands include:

sex organs, thyroid, adrenals, insulin secreting cells in the pancreas, parathyroid, etc.

Note: From here on, these are Dr. Chris DiFonzo's slides

3. Endocrine Disruption definition:

A substance that causes adverse effects in individual organisms or offspring by changing the endocrine function; e.g.,

mimic/block hormones;

affect hormonal tissue; and/or

interact with hormone receptors.

The Endocrine Disrupter Hypothesis is:

Endocrine disrupters in the environment are causing adverse reproductive, developmental, and other effects in wildlife and humans.

4. Problems in humans recently attributed to EDs:

decreased sperm counts

early puberty in females - 48% B/15% W by age 8

increase in hormone-related disease NOT related to better detection:

- Prostate cancer
- Testicular cancer
- Endometriosis

increase in birth defects

- Hypospadia
- Cryptorchidism

change in male/female birth rate

- very slight + male

5. What is known about EDs?

EDs are found in the environment

OCIs, PCBs, dioxins, etc. in sediments

also found in human and animal tissues

EDs have affected animals

C. mink in Michigan, 1960s

C. hermaphroditic fish in England

C. Lake Apopka alligators

C. 4 nony 1 phenol affecting salmon populations during spruce bud worm spraying in >70s

EDs have affected humans

C. DES in the U.S., 1945 - 1970

C. PCBs in Taiwan, 1979

6. List of proven & suspected EDs

Pesticides	Drugs
Organochlorines	DES
Pyrethroids	The Pill
Diflubenzuron	
Trainees	

EBDC fungicides

Vinclozolin

Unintentional contaminants

C. dioxins

C. polycyclic aromatic hydrocarbons (PAHs)

Natural compounds

C. genistin

C. zearlemone

C. soy-based phytoestrogens

Industrial Chemicals

C. alkyl phenol polyethoxylates (APES)

C. alkylphenols

- detergents, toiletries

C. bisphenyl A (BPA)

- dental, beverage containers -- coating in cans

C. butylated hydroxy anisole (BHA)

- preservatives in food

C. phthalates

- vinyl floors, adhesives, packaging

C. PCBs - electrical transformers

7. What is not known about EDs?

C. what is/is not an ED

C. concentration needed to affect humans

- difference in sensitivity

- timing of exposure

- multi generational effects

C. cumulative versus synergistic

- 1996 Tulane study

C. level of human exposure

8. EDs and legislation

FQPA and SDWA (safe drinking water act) both require a system of evaluating the chemicals we're manufacturing

C. both require testing

C. August 1999 deadline

C. Endocrine Disrupter Screening & Testing Advisory Committee (EDSTAC) recommendations finalized in August 1998

C. estimate of 70,000 chemicals to evaluate

European Environmental Agency Weybridge Conference, 1996

"insufficient evidence to definitely establish a causal link" between health effects seen in humans and chemical exposure.

But...although our present knowledge about environmental endocrine disrupting agents and reproduction is extremely limited, we know enough about adverse trends in reproductive health to be concerned

9. EDSTAC

Industry, Government, Environmental, Public Health, Worker Safety, Academia

Charge: Develop consensus-based recommendations for evaluating human health effects

Broadened to include wildlife

Estrogens/Androgen/Thyroid

10 EDSTAC Recommendations

87,000 cpds

Look at the riskiest first using prescreening assays

Four Categories:

- tier one screening: insufficient data to classify prescreen

- tier two: data indicate endocrine effects; proceed to whole animal studies (includes most pesticide active ingredients)

- risk assessment group: whole animal data already there; do risk assessment

- polymers: on hold - a lot of the EDs are linked to plastics

11. My Questions/Concerns

C. In vitro screening assays: how does the data relate to whole animal exposure?

C. Effects in amphibians: while this is important in environmental risk, is this important in human dietary exposure?

C. Even laboratory animals: is metabolism and hypothalamic/pituitary/sex organ or other endocrine organ similar enough to be relevant?

C. Do we have scientifically acceptable methods to predict endocrine disruption from dietary sources?

C. Reminder: you can disrupt the endocrine system by inducing liver enzymes without actually interacting

Briefing on Access To Pesticide Information

Claire Gesalman, EPA OPP Communications Branch

Following are some sources of information on pesticides at the Environmental Protection Agency and U.S. Department of Agriculture.

EPA INFORMATION SOURCES

Office of Pesticide Programs (OPP) Public Docket

Maintains the official record of a wide variety of pesticide-related actions, including the publicly released risk assessments and related documents for the organophosphates (OPs).

?. Located in Room 119, Crystal Mall 2, at 1921 Jefferson Davis Highway, Arlington, Virginia.
?. Open from 8:30 a.m. to 4:00 p.m., Monday through Friday, except Federal holidays
?. Telephone number is 703-305-5805

OPP Web Site

On various links to many pages, obtain information on the OPs, the Tolerance Reassessment Advisory Committee (TRAC), the Food Quality Protection Act (FQPA), the review of science policies, the registration and reregistration of pesticides, and other topics.

?. *www.epa.gov/pesticides/* ?the OPP home page, includes links many pesticide topics.

?. *www.epa.gov/pesticides/op/* ?the OP tolerance reassessment and reregistration home page, includes links to the OPP public docket for each OP for which documents have been released for public review, a table summarizing review status for all the OPs, information on the review process and how to become involved, background information on the OPs, and announcements of technical briefings.

?. *www.epa.gov/pesticides/trac/* ?provides access to information on and agendas for the Tolerance Reassessment Advisory Committee (TRAC), including the papers prepared for each meeting.

?. *www.epa.gov/pesticides/trac/science/* ?provides access to the draft science policy documents being released for public comment and the associated. Federal Register notice.

?. *www.epa.gov/oppbead1/matrices* ?Tables compiled by OPP to display crop-specific information about the amount of each OP pesticide used, the critical pests it is used to combat, and

available information about regional differences in use patterns.

USDA WEB SITES

The Office of Pest Management Policy serves to integrate the programs across six USDA agencies related to pest management. The following sites provide a path to the pest management programs of these agencies, or their search links, as well as the land-grant universities.

Office of Pest Management Policy (OPMP) ? *ipmwww.ncsu.edu/opmppiap* ?includes USDA?s crop profiles and other FQPA databases. The profiles are a resource for EPA in preparation of risk assessments, reregistration eligibility documents and Section 18 exemptions. The profiles also will aid USDA and others in targeting research and in developing risk mitigation plans and transition strategies.

OPMP Core Group:

Agricultural Marketing Service? *www.ams.usda.gov*
?. Pesticide Data Program ? *www.ams.usda.gov/science/pdp/index.htm*
?. Federal Pesticide Recordkeeping Program ? *www.ams.usda.gov/science/sdpr.htm*

Agricultural Research Service? *www.ars.usda.gov/*
National Programs ?*www.nps.ars.usda.gov/*
?. Animal Production , Product Value and Safety
?. Natural Resources and Sustainable Agricultural Systems
?. Crop Production, Product Value and Safety

Cooperative State Research, Education and Extension Service (CSREES) ?
www.reeusda.gov/
Plant and Animal Systems? *www.reeusda.gov/pas/programs/programs.htm*
(IPM, Interregional Projects-IR-4, Pesticide Impact Project, Pesticide Safety Education)

E?answers: Your Extension Information Source ? *www.e-answers.org/*

Economic Research Service (ERS)? *www.econ.ag.gov/*

Forest Service? *www.fs.fed.us/*

National Agricultural Statistics Service (NASS) ? *www.usda.gov/nass/*

Appendix 2

Slides for David Miller's Briefing

Appendix 3

Slides for Evelyn Washington's Briefing

Appendix 4

Speaker Bios

SPEAKER AND PANEL MEMBER BIOGRAPHIES

SPEAKERS

Mindy Lubber
EPA Region I

Mindy is the Deputy Regional Administrator for EPA-Region I, New England and is responsible for the administration and management of the 800-person, $450 million budget office as well as for overseeing the programmatic policy and legal work of the region. She personally directs the region's external affairs programs, which includes media relations and intergovernmental affairs. She's a member of the Region I senior management council. In the past she served as president of Green Century Capital Management, and investment firm dedicated to investing in environmentally responsible companies which donates all of its net revenues to supporting environmental advocacy. Mindy was a senior advisor to former Massachusetts Governor Michael Dukakis and was part of the team that ran his presidential campaign. She's held various positions with the Massachusetts Public Interest Research Group including Chairwoman of the Board of Directors and Legislative Directors. Mindy holds a bachelor's and master's in business administration and a law degree. She's a member of the Massachusetts Bar.

Jim Jones
EPA Office of Pesticide Programs

Jim is the Director of the Registration Division at EPA headquarters. Prior to that he served as the Associate Director of the Field and External Affairs Division and as the chief of the Registration Support Branch in OPP. Jim has been with EPA for 11 years. He has a Masters in Economics from the University of California at Santa Barbara and a Bachelors in Economics from the University of Maryland at College Park.

David Miller
EPA Office of Pesticide Programs

David has been with the Health Effects Division for six years, working as a residue chemist and risk assessor. The focus of his current work at EPA is probabilistic risk assessments. Prior to his agency employment he was a sanitary engineer in the Peace Corps, assigned to the Ecuadorian Ministry of Public Health. He was also an associate engineer at a health and environmental sciences consulting firm in Arlington, Virginia. HE received his bachelor's degree from the University of Pennsylvania and master's of science and master's of public health degrees from Virginia Tech and the University of Michigan, respectively. He's a commissioned officer in the U.S. Public Health Service.

PANEL MEMBERS

Robert Koethe
EPA Region I

Rob is the regional pesticide expert in the EPA-New England Office. IN that role, he provides technical support and guidance to the New England State pesticide regulatory programs. Prior to coming to work for EPA, Rob worked for eight years as the Integrated Pest Management advisor with the University of Illinois Cooperative Extension Service. Rob has a B.A. in biology from Gettysburg College, an M.S. from Penn State University, and his Ph.D. from North Carolina State University.

Lora Lee Schroeder
Life Scientist, Pesticide Section, EPA Region 4

Lora Lee is in charge of the Region 4 Agricultural Initiative, which involves emphasizing Integrated Pest Management, and the Region 4 Stewardship program. She served as a state representative for AAPCO on the TRAC committee while she was in her previous position as Pesticide Division Director of the Georgia Department of Agriculture. Ms. Schroeder has a Masters in Plant Protection & Pest Management and a Bachelors in Horticulture, both from the University of Georgia.

Evelyn Washington
EPA Office of Groundwater and Drinking Water

Evelyn is the Associate Chief of the Targeting and Analysis Branch (TAB) within the Office of Groundwater and Drinking Water. TAB is responsible for the development of regulatory tools such as cost-benefit analyses and lists of treatment technologies as well as the development of contaminant regulations such as arsenic and radon. She previously served as team leader for the Contaminant Identification and Selection Team. Ms. Washington is a chemical engineer by training and began her career at EPA in 1988. She received her bachelor's degree in Chemical Engineering from the University of Maryland, College Park. Prior to EPA, she worked for the U.S. Department of Navy.

Lebelle Hicks
Pesticide Toxicologist for Maine Department of Agriculture

Lebelle volunteered to lead the breakout session on endocrine disruptors when Christine DiFonzo was unable to come. Lebelle is the Pesticide Toxicologist for the Maine Department of Agriculture, Board of Pesticides Control. She was previously the Acting State Toxicologist for the Maine Department of Human Health and the Massachusetts Pesticide Bureau. Lebelle has a Ph.D. in Food and Nutrition Sciences from the University of Maine, an M.S. in Biology/Toxicology from Northeastern University,

and a B.S. in Biology from Fitchburg State College. She is a Diplomat of the American Board of Toxicology.

Appendix 5

Conference Evaluations

Conference Evaluation

Location
Westford Regency, Westford, MA

Registration
85 registered including speakers, walk-ins, and no-shows (14)

Evaluation Summary
Of the 71 attendees 49 turned in evaluation sheets. A summary of the evaluation follows:

Affiliation

Government - State (20), Federal (9), City (1)
Academia - Col./Univ. (8), high school (1)
Agricultural interests including growers and farm bureau (6)
Structural Pest. Control (1),
Other - Commodity group (1), private consultant (1), trade association (1)

How did attendees hear about the conference
Direct mail (20),
Internet (9),
Direct contact - telephone calls (9),
Coworkers (4),
Meetings (3),
Student newsletter (1),
Fax (1)

Rating of Conference

	Very useful	Useful	Not Useful
Status of FQPA Implementation	22	18	1
Risk, Data Needs & Assessment	25	12	1
Panel Discussion	11	23	4
Outreach on FQPA issues	7	10	3
Data Requirements	14	15	1
The Risk Cup	16	15	6
Endocrine Disruptors	10	7	6

Summary of Specific Comments by Affiliation:

States

Very informative, learned a lot of things I did not know
Any future meetings should include or involve panel discussion participation from the regulated community (growers, applicators, chemical registrants)
Would have been nice to have included a copy of the Act in the package
Appreciated the information, very helpful after reading and trying to understand FQPA on my own, have more in depth discussion; also the panel discussion was very god, but perhaps include a grower or someone directly effected on panel.
Information was very good. The rule is unworkable and I can't see how it can ever work.
Note by RISK CUP which was marked 1 - useful if only because it showed how the rule cannot work in practical application
Overall conference was very good, still don't know how the rule works, We need more information from EPA.
This meeting was very well organized and informative. Beside PANEL DISCUSSION [which marked 3 - not useful] was a notation stating that "it was interesting to get a synopsis of what different agencies purposes are"

Federal

Place conference notations in training data base.
Would have been better to have someone from OPP [Office of Pesticide Programs] who does risk assessment conduct "the risk cup" breakout session. There were lots of questions.
Talk by Region 4 staff didn?t seem relevant to our region, although she was GREAT in the Risk Cup Session.
Conference was very helpful in understanding all the issues surrounding the FQPA and its implementation.
Thanks!

Colleges and Universities

Well done!
Some decent summaries but remarkably dull presentations.
Need More time for discussions in the morning.
Should have a meeting of this sort every other year for an update on how
Things are progressing at EPA and the problems occurring for those affected by FQPA, so EPA hears these concerns. Good meeting.

Others

With proceeding, send out a glossary of terms, etc.
Good sessions
Speakers were good & well organized
Good sources of more information
Some of speakers seem to push through visuals
Concerned The FQPA will eliminate the minor uses of pesticides due to economies
More communication is needed by all parties involved, more philosophical discussion is needed in this area.
I would first like to find out what is the problem.

Appendix 6

Dr. Goldman's Q & A

Meeting on FQPA with Dr. Goldman, April 27, 1998

The meeting was attended by several Region I staff, SLA's, representatives of several commodity groups, two state IPM coordinators, and two Tuft's University people (see list).

Dr. Goldman made a few comments on the current status of FQPA, including the fact that much of the current work is being done by advisory committees; she specifically mentioned the Tolerance Assessment Advisory Committee (TRAC) which was just formed. She said no decisions have been made yet, and added that the Wall St. Journal article on the cancellation of organophosphates was totally incorrect.

Stakeholder Questions and Dr. Goldman's Answers:
Q: Rich Bonnano of NE Vegetables - how serious are you about actual use data? He said he asked this because growers were having a difficult time finding out what data was needed, and in what format.
A: Very serious. She acknowledged the confusion about the data and format and said they were working hard to get that straightened out.

Q: Follow up by Rich - How can we take a pro-active role to protect minor use crops?
A: This is tough to do; we need to involve the growers. Currently we are groping in the dark. Another aspect of this is, what are the alternatives?

Q: Jere Downing of the Cranberry Institute - are we behind the 8 ball already? We don't know what data to gather.
A: We need to be clear about the data desired, and the format in which it is presented.

Comment: Dave Bell of the Blueberry Commission - we don't know what data to collect, or how to present it to make it solid.
A: We're thinking in terms of transition. We need to achieve the goal of FQPA, but in a way that involves the stakeholders and allows a transition.

Q: Michael Corey of the Maine Potato Board - Has EPA determined the size of the risk cap for various pesticides?
A: No, the Institute of Life Sciences is working on that.

Q: Michael Corey - If a chemical is registered for several crops, how will the allowable use be determined for each?
A: The risk may be different in different regions for the same crop, as well as for different crops.

Comment: Dick Berman of Waltham Chemical - Our concern is that most of the pesticides we use are

also used in agriculture.
A: I understand that.

Q: Jere Downing - There are two key issues: time and a clear process. Another issue is confidentiality (this is a major issue with food companies).
A: There is a conflict between the desired transparency and confidentiality. I hope the companies can back off from their confidentiality requirement after the first year or so a product is on the market.

Q: Follow up, Jere Downing - adverse publicity is a concern; e.g., when the Environmental Working Group took PDP data, calculated it in their own way, and published an article which included distorted information.
A: Fear should not be a motivation. EWG did a crude assessment, not the way EPA would have done it.

Comment: Bill Coli, U. Massachusetts IPM Specialist - A concern regarding residue data is that even if a report showing zero residue is sent in, EPA will use half of the detect limit.
A: We discussed "non-detects" and got some good ideas; there is a support for using zero detects.

Q: Molly Anderson of Tufts University - How will the tolerance assessment advisory committee be constituted?
A: AT a very high level with people who are strongly networked with stakeholders. It will include about 40 people and include pest control company reps, farmer groups, structural pest control industry reps, academics, public health folks, public interest groups, and reps from state and local government.

Q: Follow up, Molly Anderson - What will be the process for public involvement?
A: All meetings will be held in public; a web site will be set up; and there will be a public comment period on each key decision.

Q: Debra VanderBeck of ACPA - Will the group have decision-making authority?
A: No, it is strictly advisory; decisions will be made by EPA.

Q: ? - What is your best guess on when the total program will be finished?
A: The TRAC will be done in August, 1998. We will then put the results in an FRN to obtain public comment; that's when you'll see our blueprint.

Q: ? - Will there be a blanket cancellation of organophosphates?
A: No.

Q: ? - I've been hearing the organophosphate risk cup is overflowing -- is there any evidence of illness

caused by exposure to organophosphates?
A: We don't know. There is a program tracking lead in blood, and they've looked for traces of organophosphates. We need to find out what is actually in people as well as in the food.

Dr. Goldman Meeting Attendees

EPA Region I
Marv Rosenstein - Associate Director, Pesticides, Toxics and Radiation
Rob Koethe - Pesticide Specialist
Andy Triolo - Pesticide Specialist
Allan Christensen - Senior Environmental Enrollee

State Lead Agencies
Connecticut - Brad Robinson
Massachusetts - Brad Mitchell, Lee Corte-Real, David Sheldon
Also Commissioner of Agriculture - Jay Healey
Rhode Island DEP - Elizabeth Lopes-Duguay
Vermont - Phil Benedict, Jim Leland

IPM Coordinators
Massachusetts - Bill Coli, Natalia Clifton, Dave Ferro
New Hampshire - Alan Eaton

Commodity groups and others
Dick Berman - Waltham Chemical
Rich Bonnano - NE Vegetables and Berries
Jere Downing - Cranberry Institute
Molly Andersen - Tufts University
David Bell - Wild Blueberry Commission of Maine
Robby Hubley - MA Audubon
Michael - Maine Potato Board
David McCarthy - Cranberry Grower
Debra Vanderbeek - NE Council for Plant Protection, & ACPA
Kelly M organ - Tufts University/Graduate Student

Appendix 7

Attendee List

EPA

Region 1, New England

Food Quality Protection Act

Proceedings of the Conference
March 3rd, 1999
Westford, Massachusetts